

US3532170 (Prod: Children's Healthcare of Atlanta)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:10:48

All time stamps listed in this document are displayed in GMT

US3532170

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:00:40

Generated On: 10 Jun 2021 08:10:48

[Participant ID](#)

US3532170

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

US3532170

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 11:03:53

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
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

US3532170

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3532170

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 11:03:48

Generated On: 10 Jun 2021 08:10:48

Were any significant conditions reported?

Yes ☒

No ☐

US3532170

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3532170

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

US3532170

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3532170

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	VIRAL ENCEPHALITIS
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3532170

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	HYPERLIPIDEMIA
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)	

US3532170

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	THUMB SURGERY
Start date (dd MMM yyyy)	25 NOV 2019
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)	25 NOV 2019
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	NOV 2019
Stop Year (derived)	2019

US3532170

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	BASILLAR THRUMB OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3532170

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	PLANTAR FASCIITIS
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)	

US3532170

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	LOW VITAMIN D LEVEL
Start date (dd MMM yyyy)	18 FEB 2020
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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3532170

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	GERD
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)	_____

US3532170

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	HYPERTENSION
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)	_____

US3532170

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3532170

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Condition	GENERALIZED MUSCLE ACHES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3532170

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 11:03:53

Generated On: 10 Jun 2021 08:10:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:26 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 10:26
Height (<i>xxx.x</i>)	152 cm
Weight (<i>xxx.x</i>)	97.8 kg
BMI (<i>xxx.x</i>)	42.33033 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532170

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 11:03:53

Generated On: 10 Jun 2021 08:10:48

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.

US3532170

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

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) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2008

Date of last menstruation unknown False

US3532170

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 11:03:53

Generated On: 10 Jun 2021 08:10:48

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 REMOTE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3532170

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 11:03:53

Generated On: 10 Jun 2021 08:10:48

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	

US3532170

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

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	VISIT1
------------	--------

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

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

What was the participant's randomization number? 188617

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 ☒

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

Height	ND - Not Done
Weight	ND - Not Done

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

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)	10:26 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 10:26
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:51
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3532170

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

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.

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

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) 11:16 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 11:16

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

US3532170

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 AUG 2020

Collection time (00:00-23:59)

10:59 (24 HR)

Collection date and time (derived)

27 AUG 2020 10:59

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

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	10:48	27 AUG 2020 10:48
Nasopharyngeal Swab 2	No		

US3532170

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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 11:54

PC Open Date & Time

27 AUG 2020 11:36

PC Close Date & Time

27 AUG 2020 14:06

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 20:28

PC Open Date & Time

27 AUG 2020 15:01

PC Close Date & Time

28 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:48

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 12:04

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:51

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:48

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:00

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 21:36

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:48

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 12:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:48

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

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 11:54

PC Open Date & Time

27 AUG 2020 11:36

PC Close Date & Time

27 AUG 2020 14:06

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

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 20:29

PC Open Date & Time

27 AUG 2020 15:01

PC Close Date & Time

28 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:48

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 12:01

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:48

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

29 AUG 2020 12:51

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:48

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

30 AUG 2020 12:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:48

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 21:36

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:48

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 12:03

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:48

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 12:04

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 11:55
PC Open Date & Time	27 AUG 2020 11:36
PC Close Date & Time	27 AUG 2020 14:06

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 20:30
PC Open Date & Time	27 AUG 2020 15:01
PC Close Date & Time	28 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 3412

EAB) (1725)

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:03
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 3412

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:52
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

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 ☒

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

62 of 3412

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 21:37
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

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 ☒

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:04
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

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

66 of 3412

EAB) (1725)

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3532170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT2

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3532170

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

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.

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3532170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3532170

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 OCT 2020

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

Comments
If Contact Not Made, please provide Comments
UNABLE TO FOLLOW UP DUE
TO SAE HOSPITALIZATION
NO VACCINE 2 WILL BE GIVEN
PER PI

US3532170

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:03:47

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:15:08

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

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

Visit date (dd MMM yyyy)	28 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
------------	--------

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 14:01
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532170

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

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.

US3532170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

14:17 (24 HR)

Collection date and time (derived)

28 OCT 2020 14:17

US3532170

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:15:09

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	27 OCT 2020 09:37:41
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 02:40:08

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

13 NOV 2020 18:52:14

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 00:02:00

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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	30 NOV 2020 12:00:56
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

05 DEC 2020 02:32:41

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

12 DEC 2020 03:00:44

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

28 DEC 2020 12:00:51

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

02 JAN 2021 12:28:48

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 12:13:55

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 15:19:30

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

23 JAN 2021 23:03:22

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

30 JAN 2021 01:21:30

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☒

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 FEB 2021 06:00:55

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☒

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 FEB 2021 09:48:50

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 FEB 2021 23:09:40
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

27 FEB 2021 07:23:51

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☒

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

07 MAR 2021 23:03:45

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 19:21:40

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

20 MAR 2021 00:53:06

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

27 MAR 2021 02:54:55

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 <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	03 APR 2021 01:53:20
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

10 APR 2021 00:07:01

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

19 APR 2021 20:17:46

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 21:03:13

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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="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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 <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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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	09 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	13 OCT 2021 23:59
---	-------------------

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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	23 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	27 OCT 2021 23:59
---	-------------------

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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	25 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	29 DEC 2021 23:59
---	-------------------

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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°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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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="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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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="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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 <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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 <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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	17 AUG 2022 23:59
---	-------------------

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 <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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐
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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐ 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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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
---	-------------------

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3532170

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:10:48

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		10 MAR 2021 15:51:40

US3532170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:40:28

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:40:28

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:01:09

Generated On: 10 Jun 2021 08:10:48

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

Visit date (dd MMM yyyy)	10 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
------------	--------

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:01:09

Generated On: 10 Jun 2021 08:10:48

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) _____

US3532170

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:01:09

Generated On: 10 Jun 2021 08:10:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 MAR 2021

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

US3532170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 MAR 2021

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

10 MAR 2021 11:40

US3532170

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:17:41

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:17:41

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532170

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:48

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"/>

US3532170

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:10:48

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3532170

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

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

Visit date (dd MMM yyyy)	2 FEB 2021
--------------------------	------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3532170

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Date of updated informed consent (<i>dd MMM yyyy</i>)	2 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	2 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3532170

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3532170

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	2 FEB 2021
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 13:30
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3532170

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 FEB 2021
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 15:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3532170

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

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

US3532170

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 14:31 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 14:31

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

US3532170

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 FEB 2021

Collection time (00:00-23:59)

14:06 (24 HR)

Collection date and time (derived)

2 FEB 2021 14:06

US3532170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00 - 23:59)	13:55
Collection Date and Time (derived)	2 FEB 2021 13:55

US3532170

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3532170

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	OLD29

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

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)	10 MAR 2021
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 11:18
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 MAR 2021
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 12:39
Temperature (xxx.x)	98.9 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3532170

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 MAR 2021

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

US3532170

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 10 MAR 2021

What was the treatment time? (00:00-23:59) 12:05 (24 HR)

Treatment Date and Time (derived) 10 MAR 2021 12:05

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

US3532170

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532170

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532170

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 08:26:24

Generated On: 10 Jun 2021 08:10:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 08:26:24

Generated On: 10 Jun 2021 08:10:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 APR 2021
Time of assessment (<i>00:00-23:59</i>)	11:28 (24 HR)
Vital Signs Date and Time (derived)	8 APR 2021 11:28
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532170

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 08:26:24

Generated On: 10 Jun 2021 08:10:48

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.

US3532170

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 08:26:24

Generated On: 10 Jun 2021 08:10:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 APR 2021
Collection time (00:00-23:59)	11:28 (24 HR)
Collection date and time (derived)	8 APR 2021 11:28

US3532170

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 09:13:30

Generated On: 10 Jun 2021 08:10:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	USA-US077-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE MYOCARDIAL INFARTION
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)	07 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)	6 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)	07 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	6 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	323 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

Number of Days in ICU	9
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	VENTRICULAR FIBRILLATION-INTERMEDIATE, ANXIETY, WHEEZING
Narrative	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

SUBJECT REPORTED ON 15SEP
202 SUFFERING ACUTE MI ON
07SEP2020 AND HAVING
EMERGENCY BYPASS
SURGERY. HISTORY OF
HYPERTENSION, TYPE II
DIABETES AND
HYPERLIPIDEMIA BUT
UNAWARE OF ANY ACUTE
RISK.
PI: WOULD CONSIDER THIS
UNRELATED TO VACCINE,
INSTEAD RELATED TO HER
UNDERLYING TYPE 2
DIABETES, HYPERLIPIDEMIA
AND HYPERTENSION. TIMING
IS AT 10 DAYS AFTER
VACCINATION WHICH ALSO
MAKES IT LESS LIKELY TO BE
RELATED.

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

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	
Adverse event	ANXIETY POST CABG
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)	06 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

326 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	SUBJECT PLACED ON MEDICATION AND DX WITH ANXIETY PER CARDIAC TEAM AFTER MI AN POST CABG
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)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

327 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	
Adverse event	NAUSEA
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)	12 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 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 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

328 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SEVERE NAUSEA RELATED TO MEDICATION TAKEN DURING HOSPITALIZATION. MEDICATIONS CHANGED AND SUBJECT ABLE TO STOP ZOFRAN
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	329 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID

Adverse event

VENTRICULAR FIBRILLATION-
INTERMEDIATE

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)

08 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)

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

331 of 3412

EAB) (1725)

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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 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	PLACED ON MEDS TO TREAT, DUE TO MI
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)	

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	
Adverse event	BEDSORE
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)	13 NOV 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

333 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with 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	OCCURRED AFTER HER SAE- DUE TO SAE AND NOT DUE TO STUDY PRODUCT
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)	

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID

Adverse event

SHORTNESS OF BREATH-
ETIOLOGY UNKNOWN,
SUSPECT MEDIATION
INDUCED, NOT COVID-19.
LIMITED EPISODE.

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 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

PRODUCTION RELEASE (v12.003

335 of 3412

EAB) (1725)

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

	No	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
<hr/>		
Persistent or significant disability or incapacity	False	<input type="radio"/>
<hr/>		
Congenital anomaly or birth defect	False	<input type="radio"/>
<hr/>		
Other medically important event	False	<input type="radio"/>
<hr/>		
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
<hr/>		
Other action taken (check all that apply)		
<hr/>		
None	False	<input type="radio"/>
<hr/>		
Concomitant Medication	True	<input type="radio"/>
<hr/>		
Concomitant Procedure	False	<input type="radio"/>
<hr/>		
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input checked="" type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative	SEEN BY CARDIOLOGIST, ECHO AND EVENT MONITOR. CHANGE IN LISINOPRIL.	
<hr/>		
Serious Adverse Event Derived (CSA Programming Field Only)	0	
<hr/>		

PRODUCTION RELEASE (v12.003
EAB) (1725)

336 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	
Adverse event	SYNCOPE
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)	14 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	
Adverse event	BENIGN INTENTION TREMORS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

340 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	USA-US077-2021-MRNA-1273-P30 1000003
Adverse event	WOUND INFECTION LEFT BUTTOCK
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)	17 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	24 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	342 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

BEDSORE POST CABAG 9/2020.
TREATED FOR INFECTION NOV
2020. WOUND VAC DRAIN
PLACED 20JAN DUE TO
BEDSORE NOT HEALING.
SUBJECT IS DIABETIC.
SUBJECCT WITH EVER CHILLS
AND WORSENING BEDSORE
2/17/20 AND ADMITTED TO
HOSPITAL 2/19/2020 FOR IV
ANTIBIOTICS

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

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	USA-US077-2021-MRNA-1273-P30 1000003
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	24 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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	INFECTED BEDSORE. SYMPTOMS OF HYPOTENSION, FEVER 102.6F AND LEUKOCYTOSIS. BLOOD CULTURES PENDING. CURRENTLY ON ROCEPHIN AND VANCOMYCIN

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	
Adverse event	BILATERAL LEG SWELLING
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)	14 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AEID	
Adverse event	WHEEZING
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)	14 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)	18 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

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

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

AE OCCURRED DURING
HOSPITALIZATION 07SEP2020
UNTIL 06OCT2020 AND WAS
NOT RELATED TO
HOSPITALIZATION OR
PROLONGED
HOSPITALIZATION BUT WAS
SECONDARY TO PRIMARY
DIAGNOSIS ACUTE
MYOCARDIAL INFARCTION

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

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

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

Yes ☒

No ☐

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

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

356 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 1985
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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication LANTUS INSULIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 18

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

360 of 3412

EAB) (1725)

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 OCT 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"/>	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication MULTI-VITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

362 of 3412

EAB) (1725)

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 1985
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN SEP 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"/>	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

364 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 FEB 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED MUSCLE ACHES

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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) _____		
Start date completely unknown		True
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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication ACETAMINOPHEN-HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION-
POST CABG TREATMENT
PROTOCOL

Dose per administration 325 / 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 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)		19 SEP 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 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)	01 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

372 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	13 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)		UN NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

376 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	14 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)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication VENELEX

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	14 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)	12 OCT 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication COLACE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)		14 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	6 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)	8 OCT 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 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)		12 OCT 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

386 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)		14 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)		01 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		6 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication GUAIFENESIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

390 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	UN 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)	29 SEP 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

392 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	6 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)	19 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 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)	14 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 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) UN NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)		14 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)		28 OCT 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY POST CABG

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

400 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	6 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)		14 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

402 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 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)		9 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication BISACODYL

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 checked="" type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 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)		12 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION
POST CABG TREATMENT
PROTOCOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication SENNA

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTIN
POST CABG TREATMENT
PROTOCOL

Dose per administration 17.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

410 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication PHENERGAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

412 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 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)		04 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication AMPICILLIN

Prophylaxis Yes ☐
No ☒

Indication INFECTED WOUND- BEDSORE

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

418 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

420 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication ANXIETY POST CABAG

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

422 of 3412

EAB) (1725)

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	14 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

424 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 AUG 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication AMOXICILLIN/CLAVULANATE

Prophylaxis Yes ☐
No ☒

Indication WOUND INFECTION- LEFT
BUTTOCK

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

426 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS/WOUND INFECTION
LEFT BUTTOCK

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication WOUND INFECTION LEFT
BUTTOCK/SEPSIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

430 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	23 FEB 2021	
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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS/WOUND INFECTION
LEFT BUTTOCK

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)

432 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	21 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	24 FEB 2021	
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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

434 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication METOPROLOL SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

436 of 3412

EAB) (1725)

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	14 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	16 APR 2021	
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"/>	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication BILATERAL LEG SWELLING

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

438 of 3412

EAB) (1725)

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)	14 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication FLAGYL

Prophylaxis Yes ☐
No ☒

Indication SEPSIS/WOUND INFECTION
LEFT BUTTOCK

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

440 of 3412

EAB) (1725)

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication WHEEZING

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

442 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 SEP 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication INSULIN LISPRO

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 100/30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

444 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication IPRATROPIUM

Prophylaxis Yes ☐
No ☒

Indication WHEEZING

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

446 of 3412

EAB) (1725)

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 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)		18 SEP 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

448 of 3412

EAB) (1725)

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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)		14 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) 18 SEP 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"/>	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication HYDRALAZINE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

450 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 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)		13 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

452 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 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) 13 SEP 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication MILRINONE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

454 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 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) 14 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"/>

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

Name of Medication METOPROLOL SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

456 of 3412

EAB) (1725)

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 22 Apr 2021 15:17:40

Generated On: 10 Jun 2021 08:10:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 16:09:16

Generated On: 10 Jun 2021 08:10:48

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 SEP 2020	CABG X 2	Adverse Event	
27 NOV 2020	BEDSORE WOUND DEBRIDEMENT	Adverse Event	
20 JAN 2021	WOUND VAC PLACEMENT	Adverse Event	
21 FEB 2021	BLOOD CULTURE	Adverse Event	
19 FEB 2021	CT OF ABD AND PELVIS WITH CONTRAST	Adverse Event	
20 NOV 2020	ECHOCARDIOGRAM	Adverse Event	
19 NOV 2020	EVENT MONITOR (WORE FOR 2 WEEKS)	Adverse Event	
19 FEB 2021	HEMATOLOGY DRAW	Adverse Event	
20 FEB 2021	HEMATOLOGY DRAW	Adverse Event	

US3532170

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 20:00:42

Generated On: 10 Jun 2021 08:10:48

Date of dosing discontinuation (dd MMM yyyy) 2 OCT 2020

Primary reason for dosing discontinuation

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

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

SAE #1

US3532170

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:10:48

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 ☐

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2020-MRNA-1273-P301000001
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2020-MRNA-1273-P301000001
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/SEP/2020 09:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2020-MRNA-1273-P301000001
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/OCT/2020 19:18
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

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2020-MRNA-1273-P301000001
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/OCT/2020 12:08
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

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2020-MRNA-1273-P301000001
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/OCT/2020 15:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2020-MRNA-1273-P301000001
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/OCT/2020 19:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2020-MRNA-1273-P301000001
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/NOV/2020 06:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 20 Apr 2021 15:49:44

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2020-MRNA-1273-P301000001
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/APR/2021 12:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2021-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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2021-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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/FEB/2021 13:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2021-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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/MAR/2021 13:16
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

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2021-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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/MAR/2021 16:18
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

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2021-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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 10:41
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

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:00:43

Generated On: 10 Jun 2021 08:10:48

SAEID	USA-US077-2021-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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/MAR/2021 09:53
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

US3532170 (Prod: Children's Healthcare of Atlanta)

US3532170

Form: Participant Creation

Generated On: 10 Jun 2021 08:10:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'US3532170'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 14:34:39

US3532170

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:11

US3532170

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 14:34:40

US3532170

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:11

US3532170

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'SCRN'	System	27 Aug 2020 14:35:11

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 14:34:41

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '66'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'YEARS'	System	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '66'	System	27 Aug 2020 14:44:26

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Female (F)'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'I'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 14:35:27

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 14:44:26

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Aug 2020'	System	27 Aug 2020 14:44:26

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2020'	System	27 Aug 2020 14:44:26

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Amendment 3 (3)'	Lisa Macoy (b) (4)	27 Aug 2020 14:44:26

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 14:44:26

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 14:44:26

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 14:44:26

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 14:44:26

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 14:34:40

US3532170

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'I'	System	27 Aug 2020 14:44:53

US3532170

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 14:44:53

US3532170

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:10:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:47:34

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:08:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:08:39
Data point term sent to Coder	System	28 Aug 2020 17:08:05
User entered 'type II diabetes'	Lisa Macoy (b) (4)	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 2016'	Lisa Macoy (b) (4)	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 2016'	System	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2016'	System	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:07:29

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:09:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:09:41
Data point term sent to Coder	System	28 Aug 2020 17:09:07
User entered 'hypothyroidism'	Lisa Macoy (b) (4)	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 1985'	Lisa Macoy (b) (4)	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 1985'	System	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '1985'	System	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:08:09

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:09:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:09:41
Data point term sent to Coder	System	28 Aug 2020 17:09:08
User entered 'seasonal allergies'	Lisa Macoy (b) (4)	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'I'	Lisa Macoy (b) (4)	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:08:45

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Encephalitis viral, LLT: Viral encephalitis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:10:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:10:43
Data point term sent to Coder	System	28 Aug 2020 17:10:08
User entered 'viral encephalitis'	Lisa Macoy (b) (4)	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 1975'	Lisa Macoy (b) (4)	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 1975'	System	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '1975'	System	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:09:29

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
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.	(b) (4) Coders Import (b) (4) (b) (4)	28 Aug 2020 17:10:43
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	Coders Import (b) (4) (b) (4)	28 Aug 2020 17:10:43
Data point term sent to Coders System	System	28 Aug 2020 17:10:11
User entered 'hyperlipidemia'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 2017'	Lisa Macoy (b) (4)	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 2017'	System	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2017'	System	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:09:50

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:39:09
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'indication listed- arthritis ' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	16 Oct 2020 13:33:25
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:17:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb operation, LLT: Finger operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:11:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:11:45
Data point term sent to Coder	System	28 Aug 2020 17:11:13
User entered 'thumb surgery'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '25 Nov 2019'	Lisa Macoy (b) (4)	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '25 Nov 2019'	Lisa Macoy (b) (4)	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Nov 2019'	System	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2019'	System	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Nov 2019'	System	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2019'	System	28 Aug 2020 17:10:41

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User closed query 'Per DM CLR: Please specify the type of BASILLAR THUMB ARTHRITIS (Rheumatoid versus Osteoarthritis) as well as the laterality (bilateral, left, right). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 04:41:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Thumb osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 04:12:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 04:12:12
Data point term sent to Coder	System	26 Oct 2020 18:57:41
Query 'Per DM CLR: Please specify the type of BASILLAR THUMB ARTHRITIS (Rheumatoid versus Osteoarthritis) as well as the laterality (bilateral, left, right). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	Lisa Macoy (b) (4) (b) (4)	26 Oct 2020 18:56:55
' answered with 'updated' (Site from DM).		
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	26 Oct 2020 18:56:50
User entered 'BASILLAR THRUMB OSTEOARTHRITIS' reason for change: Per Query Resolution	Lisa Macoy (b) (4) (b) (4)	26 Oct 2020 18:56:50
User opened query 'Per DM CLR: Please specify the type of BASILLAR THUMB ARTHRITIS (Rheumatoid versus Osteoarthritis) as well as the laterality (bilateral, left, right). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:39:11

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Finger arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 07:25:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 07:25:51
Data point term sent to Coder	System	28 Aug 2020 17:11:13
User entered 'Basillar thrumb arthritis'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 2016'	Lisa Macoy (b) (4)	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 2016'	System	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2016'	System	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:11:09

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Plantar fasciitis, LLT: Plantar fasciitis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:14:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:14:39
Data point term sent to Coder	System	28 Aug 2020 17:13:17
User entered 'plantar fasciitis'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:20
	(b) (4)	

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 2018'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:20

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:20

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:20

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:12:20

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:20

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 2018'	System	28 Aug 2020 17:12:20

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2018'	System	28 Aug 2020 17:12:20

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:12:20

US3532170

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:12:20

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Investigations, HLT: Metabolic, nutritional and blood gas investigations, HLT: Vitamin analyses, PT: Vitamin D decreased, LLT: Vitamin D low - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:14:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:14:40
Data point term sent to Coder	System	28 Aug 2020 17:13:18
User entered 'low Vitamin D level'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '18 Feb 2020'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Feb 2020'	System	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2020'	System	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:12:40

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:14:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:14:39
Data point term sent to Coder	System	28 Aug 2020 17:13:18
User entered 'GERD'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 1995'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 1995'	System	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '1995'	System	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:12:59

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Oct 2020 21:59:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:59:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:15:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:15:43
Data point term sent to Coder	System	28 Aug 2020 17:14:19
User entered 'bilateral cataract surgery'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 2002'	Lisa Macoy (b) (4)	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 2002'	Lisa Macoy (b) (4)	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 2002'	System	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2002'	System	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 2002'	System	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2002'	System	28 Aug 2020 17:13:30

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:23:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:23:59
Data point term sent to Coder	System	28 Aug 2020 17:22:37
User entered 'hypertension'	Lisa Macoy (b) (4)	28 Aug 2020 17:22:27
	(b) (4)	

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 2015'	Lisa Macoy (b) (4)	28 Aug 2020 17:22:27

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:22:27

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:22:27

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:22:27

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:22:27

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 2015'	System	28 Aug 2020 17:22:27

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2015'	System	28 Aug 2020 17:22:27

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:22:27

US3532170

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	28 Aug 2020 17:22:27

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 13:35:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 13:35:25
Data point term sent to Coder	System	16 Oct 2020 13:34:35
User entered 'menopause'	Lisa Macoy (b) (4)	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 2008'	Lisa Macoy (b) (4)	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'Jan 2008'	System	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '2008'	System	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	16 Oct 2020 13:34:35

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 13:53:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 13:53:40
Data point term sent to Coder	System	09 Nov 2020 13:53:38
User entered 'Generalized muscle aches'	Lisa Macoy (b) (4)	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'I'	Lisa Macoy (b) (4)	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered empty.	System	09 Nov 2020 13:53:27

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '10:26'	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered '27 Aug 2020 10:26'	System	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '152' cm	(b) (4) Lisa Macoy (b) (4)	27 Aug 2020 15:44:25
DataPoint set to visible.	(b) (4) System	27 Aug 2020 14:44:53

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '97.8' kg	(b) (4) Lisa Macoy (b) (4)	27 Aug 2020 15:44:25
DataPoint set to visible.	(b) (4) System	27 Aug 2020 14:44:53

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
Amendment Manager: User entered '42.33033'	System	17 Sep 2020 00:05:05
User entered '42.3'	System	27 Aug 2020 15:44:25
DataPoint set to visible.	System	27 Aug 2020 14:44:53

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'kg/m2'	System	27 Aug 2020 15:44:25
DataPoint set to visible.	System	27 Aug 2020 14:44:53

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'bpm'	System	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'breaths/min'	System	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'mmHg'	System	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User entered 'mmHg'	System	27 Aug 2020 15:44:25

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08

US3532170

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08

US3532170

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:44:36

US3532170

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 15:44:36

US3532170

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 14:45:50

US3532170

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:48

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 14:45:50

US3532170

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:48

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 07:26:55
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	16 Oct 2020 13:33:50
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:22:56
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Lisa Macoy (b) (4) (b) (4)	27 Aug 2020 14:45:50

US3532170

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:48

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 14:45:50

US3532170

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 14:45:50

US3532170

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:48

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 14:45:50

US3532170

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'un UNK 2008'	Lisa Macoy (b) (4)	27 Aug 2020 14:45:50

US3532170

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 14:45:50

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

[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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

[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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'remote'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

[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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered 'I'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered '0'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:13:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:53
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 15:45:02

US3532170

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 14:44:44

US3532170

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 14:44:44

US3532170

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	27 Aug 2020 14:44:44

US3532170

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'VISIT1'	System	27 Aug 2020 14:44:44

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 14:54:36

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:48

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '188617'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 14:54:36

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 14:54:36

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:48

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)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:20

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:48

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)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 15:45:28
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	27 Aug 2020 15:45:28
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	27 Aug 2020 15:45:20
	Lisa Macoy (b) (4)	27 Aug 2020 15:45:20
	(b) (4)	

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:20

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:20

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:20

US3532170

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Etza Peters (b) (4)	25 Sep 2020 16:04:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:13:09
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:13:08

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Macoy (b) (4) (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Aug 2020 15:54:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	27 Aug 2020 15:54:13
User entered '10:26' reason for change: Data Entry Error	Lisa Macoy (b) (4)	27 Aug 2020 15:54:13
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Aug 2020 15:54:01
User entered empty.	System	27 Aug 2020 15:54:01
	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01
	(b) (4)	

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered '27 Aug 2020 10:26'	System	27 Aug 2020 15:54:13
User entered empty.	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	27 Aug 2020 15:54:19
User entered '98.9' F reason for change: Data Entry Error	System	27 Aug 2020 15:54:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01
User entered '98.9' (non-conformant).	(b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '92'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'bpm'	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '20'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'breaths/min'	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '123'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'mmHg'	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '78'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'mmHg'	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Macoy (b) (4) (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '11:51'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered '27 Aug 2020 11:51'	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '98.9' F	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '87'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'bpm'	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '20'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'breaths/min'	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '102'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'mmHg'	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '68'	Lisa Macoy (b) (4)	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'mmHg'	System	27 Aug 2020 15:54:01

US3532170

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:38

US3532170

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 15:45:38

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '11:16'	Lisa Macoy (b) (4)	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered '27 Aug 2020 11:16'	System	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Right Arm (RIGHT ARM)'	Lisa Macoy (b) (4)	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'ONCE'	System	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 15:46:10

US3532170

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:46:28

US3532170

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 15:46:28

US3532170

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '10:59'	Lisa Macoy (b) (4)	27 Aug 2020 15:46:28

US3532170

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered '27 Aug 2020 10:59'	System	27 Aug 2020 15:46:28

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '27 Aug 2020'	Lisa Macoy (b) (4)	27 Aug 2020 15:47:18

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lisa Macoy (b) (4) (b) (4)	27 Aug 2020 15:47:18

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:47:18

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '10:48'	Lisa Macoy (b) (4)	27 Aug 2020 15:47:18

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered '27 Aug 2020 10:48'	System	27 Aug 2020 15:47:18

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lisa Macoy (b) (4) (b) (4)	27 Aug 2020 15:47:18

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	27 Aug 2020 15:47:18

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	27 Aug 2020 15:47:18

US3532170

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered empty.	System	27 Aug 2020 15:47:18

US3532170

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Aug 2020 15:55:57

US3532170

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'I'	System	27 Aug 2020 15:55:57

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:53:26', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e05dfa27-ca8a-4503-87ec-c671c3aacbe8' User entered 'Yes (Y)'	System	27 Aug 2020 15:54:08
	System	27 Aug 2020 15:54:08

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:53:48', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e05dfa27-ca8a-4503-87ec-c671c3aacbe8' User entered '98.9'	System	27 Aug 2020 15:54:08
	System	27 Aug 2020 15:54:08

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:53:54', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e05dfa27-ca8a-4503-87ec-c671c3aacbe8'	System	27 Aug 2020 15:54:08
User entered 'No (N)'	System	27 Aug 2020 15:54:08

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:54:06', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e05dfa27-ca8a-4503-87ec-c671c3aacbe8' User entered '27 Aug 2020 11:54'	System	27 Aug 2020 15:54:08
	System	27 Aug 2020 15:54:08

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '27 Aug 2020 11:36'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '27 Aug 2020 14:06'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:28:27', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8923fb2d-e6fb-47f5-8e8e-b16290e5d07f' User entered 'Yes (Y)'	System	28 Aug 2020 00:28:55
	System	28 Aug 2020 00:28:55

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:28:35', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8923fb2d-e6fb-47f5-8e8e-b16290e5d07f' User entered '98.1'	System	28 Aug 2020 00:28:55
	System	28 Aug 2020 00:28:55

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:28:39', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8923fb2d-e6fb-47f5-8e8e-b16290e5d07f' User entered 'No (N)'	System	28 Aug 2020 00:28:55
	System	28 Aug 2020 00:28:55

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:28:50', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8923fb2d-e6fb-47f5-8e8e-b16290e5d07f' User entered '27 Aug 2020 20:28'	System	28 Aug 2020 00:28:55
	System	28 Aug 2020 00:28:55

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '27 Aug 2020 15:01'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 2'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:04:15', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e6498273-86ed-4f4c-8976-be67cc0de03b' User entered 'Yes (Y)'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:04:23', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e6498273-86ed-4f4c-8976-be67cc0de03b' User entered '97.4'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:04:35', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e6498273-86ed-4f4c-8976-be67cc0de03b'	System	28 Aug 2020 16:05:42
User entered 'No (N)'	System	28 Aug 2020 16:05:42

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:04:42', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e6498273-86ed-4f4c-8976-be67cc0de03b' User entered '28 Aug 2020 12:04'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 3'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:48

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:50:47', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '2ada3d82-3497-4d12-adbf-aff0d96cb50d' User entered 'Yes (Y)'	System	29 Aug 2020 16:51:13
	System	29 Aug 2020 16:51:13

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:50:54', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '2ada3d82-3497-4d12-adbf-aff0d96cb50d' User entered '97.7'	System	29 Aug 2020 16:51:13
	System	29 Aug 2020 16:51:13

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:50:59', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '2ada3d82-3497-4d12-adbf-aff0d96cb50d'	System	29 Aug 2020 16:51:13
User entered 'No (N)'	System	29 Aug 2020 16:51:13

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:51:12', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '2ada3d82-3497-4d12-adbf-aff0d96cb50d' User entered '29 Aug 2020 12:51'	System	29 Aug 2020 16:51:13
	System	29 Aug 2020 16:51:13

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 4'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:00:29', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '596ffc67-a105-4d97-a4ba-b6b613ccfc83'	System	30 Aug 2020 16:00:56
User entered 'Yes (Y)'	System	30 Aug 2020 16:00:56

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:00:37', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '596ffc67-a105-4d97-a4ba-b6b613ccfc83' User entered '98.4'	System	30 Aug 2020 16:00:56
	System	30 Aug 2020 16:00:56

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:00:41', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '596ffc67-a105-4d97-a4ba-b6b613ccfc83'	System	30 Aug 2020 16:00:56
User entered 'No (N)'	System	30 Aug 2020 16:00:56

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:00:46', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '596ffc67-a105-4d97-a4ba-b6b613ccfc83'	System	30 Aug 2020 16:00:56
User entered '30 Aug 2020 12:00'	System	30 Aug 2020 16:00:56

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 5'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:35:40', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd4f29009-e008-4c45-8329-f0eff93a66a9' User entered 'Yes (Y)'	System	01 Sep 2020 01:36:05
	System	01 Sep 2020 01:36:05

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:35:49', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd4f29009-e008-4c45-8329-f0eff93a66a9' User entered '97.7'	System	01 Sep 2020 01:36:05
	System	01 Sep 2020 01:36:05

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:35:55', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd4f29009-e008-4c45-8329-f0eff93a66a9' User entered 'No (N)'	System	01 Sep 2020 01:36:05
	System	01 Sep 2020 01:36:05

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:02', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd4f29009-e008-4c45-8329-f0eff93a66a9'	System	01 Sep 2020 01:36:05
User entered '31 Aug 2020 21:36'	System	01 Sep 2020 01:36:05

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 6'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:02:14', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '092f5d85-1e3a-42b0-ba38-e94dbe8afafa' User entered 'Yes (Y)'	System	01 Sep 2020 16:03:31
	System	01 Sep 2020 16:03:31

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:02:21', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '092f5d85-1e3a-42b0-ba38-e94dbe8afafa' User entered '99.1'	System	01 Sep 2020 16:03:31
	System	01 Sep 2020 16:03:31

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:02:25', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '092f5d85-1e3a-42b0-ba38-e94dbe8afafa' User entered 'No (N)'	System	01 Sep 2020 16:03:31
	System	01 Sep 2020 16:03:31

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:02:45', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '092f5d85-1e3a-42b0-ba38-e94dbe8afafa' User entered '01 Sep 2020 12:02'	System	01 Sep 2020 16:03:31
	System	01 Sep 2020 16:03:31

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 7'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:02:35', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8a77f869-4930-4974-8f44-9ff7a9b3fad0' User entered 'Yes (Y)'	System	02 Sep 2020 16:04:04
	System	02 Sep 2020 16:04:04

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:03:02', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8a77f869-4930-4974-8f44-9ff7a9b3fad0' User entered '97.1'	System	02 Sep 2020 16:04:04
	System	02 Sep 2020 16:04:04

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:03:16', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8a77f869-4930-4974-8f44-9ff7a9b3fad0'	System	02 Sep 2020 16:04:04
User entered 'No (N)'	System	02 Sep 2020 16:04:04

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:03:22', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8a77f869-4930-4974-8f44-9ff7a9b3fad0' User entered '02 Sep 2020 12:03'	System	02 Sep 2020 16:04:04
	System	02 Sep 2020 16:04:04

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:54:21', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b8086798-2165-42a8-8172-7bfb8f30e76b' User entered 'None (1)'	System	27 Aug 2020 15:54:48
	System	27 Aug 2020 15:54:48

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:54:25', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b8086798-2165-42a8-8172-7bfb8f30e76b' User entered 'No (N)'	System	27 Aug 2020 15:54:48
	System	27 Aug 2020 15:54:48

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:54:29', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b8086798-2165-42a8-8172-7bfb8f30e76b' User entered 'No (N)'	System	27 Aug 2020 15:54:48
	System	27 Aug 2020 15:54:48

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:54:36', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b8086798-2165-42a8-8172-7bfb8f30e76b' User entered 'None (1)'	System	27 Aug 2020 15:54:48
	System	27 Aug 2020 15:54:48

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:54:45', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b8086798-2165-42a8-8172-7bfb8f30e76b' User entered '27 Aug 2020 11:54'	System	27 Aug 2020 15:54:48
	System	27 Aug 2020 15:54:48

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '27 Aug 2020 11:36'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '27 Aug 2020 14:06'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:28:58', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '563d7479-0d61-4402-9aa6-2d4f9a5d691d' User entered 'None (1)'	System	28 Aug 2020 00:29:20
	System	28 Aug 2020 00:29:20

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:02', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '563d7479-0d61-4402-9aa6-2d4f9a5d691d' User entered 'No (N)'	System	28 Aug 2020 00:29:20
	System	28 Aug 2020 00:29:20

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:05', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '563d7479-0d61-4402-9aa6-2d4f9a5d691d' User entered 'No (N)'	System	28 Aug 2020 00:29:20
	System	28 Aug 2020 00:29:20

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:09', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '563d7479-0d61-4402-9aa6-2d4f9a5d691d' User entered 'None (1)'	System	28 Aug 2020 00:29:20
	System	28 Aug 2020 00:29:20

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:17', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '563d7479-0d61-4402-9aa6-2d4f9a5d691d' User entered '27 Aug 2020 20:29'	System	28 Aug 2020 00:29:20
	System	28 Aug 2020 00:29:20

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '27 Aug 2020 15:01'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 2'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:01:01', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'f98a7794-c306-409b-9cef-966f68572a7e'	System	28 Aug 2020 16:02:11
User entered 'None (1)'	System	28 Aug 2020 16:02:11

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:01:06', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'f98a7794-c306-409b-9cef-966f68572a7e'	System	28 Aug 2020 16:02:11
User entered 'No (N)'	System	28 Aug 2020 16:02:11

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:01:10', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'f98a7794-c306-409b-9cef-966f68572a7e' User entered 'No (N)'	System	28 Aug 2020 16:02:11
	System	28 Aug 2020 16:02:11

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:01:17', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'f98a7794-c306-409b-9cef-966f68572a7e' User entered 'None (1)'	System	28 Aug 2020 16:02:11
	System	28 Aug 2020 16:02:11

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:01:27', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'f98a7794-c306-409b-9cef-966f68572a7e' User entered '28 Aug 2020 12:01'	System	28 Aug 2020 16:02:11
	System	28 Aug 2020 16:02:11

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 3'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:51:18', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'aa8e0c9b-7edb-41c2-b496-79f9607e7e9b'	System	29 Aug 2020 16:51:45
User entered 'None (1)'	System	29 Aug 2020 16:51:45

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:51:29', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'aa8e0c9b-7edb-41c2-b496-79f9607e7e9b' User entered 'No (N)'	System	29 Aug 2020 16:51:45
	System	29 Aug 2020 16:51:45

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:51:32', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'aa8e0c9b-7edb-41c2-b496-79f9607e7e9b' User entered 'No (N)'	System	29 Aug 2020 16:51:45
	System	29 Aug 2020 16:51:45

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:51:36', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'aa8e0c9b-7edb-41c2-b496-79f9607e7e9b'	System	29 Aug 2020 16:51:45
User entered 'None (1)'	System	29 Aug 2020 16:51:45

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:51:43', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'aa8e0c9b-7edb-41c2-b496-79f9607e7e9b' User entered '29 Aug 2020 12:51'	System	29 Aug 2020 16:51:45
	System	29 Aug 2020 16:51:45

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 4'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:00:57', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '178a192c-9a38-43b9-9874-11e40d1ff6a5'	System	30 Aug 2020 16:02:27
User entered 'None (1)'	System	30 Aug 2020 16:02:27

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:01:01', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '178a192c-9a38-43b9-9874-11e40d1ff6a5'	System	30 Aug 2020 16:02:27
User entered 'No (N)'	System	30 Aug 2020 16:02:27

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:01:04', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '178a192c-9a38-43b9-9874-11e40d1ff6a5' User entered 'No (N)'	System	30 Aug 2020 16:02:27
	System	30 Aug 2020 16:02:27

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:01:15', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '178a192c-9a38-43b9-9874-11e40d1ff6a5'	System	30 Aug 2020 16:02:27
User entered 'None (1)'	System	30 Aug 2020 16:02:27

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:01:53', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '178a192c-9a38-43b9-9874-11e40d1ff6a5' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:02:27
	System	30 Aug 2020 16:02:27

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 5'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:11', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '10b36fae-57a4-479f-bf6d-9cc1b2c94b72'	System	01 Sep 2020 01:36:33
User entered 'None (1)'	System	01 Sep 2020 01:36:33

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:15', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '10b36fae-57a4-479f-bf6d-9cc1b2c94b72'	System	01 Sep 2020 01:36:33
User entered 'No (N)'	System	01 Sep 2020 01:36:33

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:19', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '10b36fae-57a4-479f-bf6d-9cc1b2c94b72'	System	01 Sep 2020 01:36:33
User entered 'No (N)'	System	01 Sep 2020 01:36:33

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:23', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '10b36fae-57a4-479f-bf6d-9cc1b2c94b72'	System	01 Sep 2020 01:36:33
User entered 'None (1)'	System	01 Sep 2020 01:36:33

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:31', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '10b36fae-57a4-479f-bf6d-9cc1b2c94b72'	System	01 Sep 2020 01:36:33
User entered '31 Aug 2020 21:36'	System	01 Sep 2020 01:36:33

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 6'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:02:56', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de59fa73-c7b1-4f6f-82f7-919a10887f57'	System	01 Sep 2020 16:04:04
User entered 'None (1)'	System	01 Sep 2020 16:04:04

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:03:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de59fa73-c7b1-4f6f-82f7-919a10887f57'	System	01 Sep 2020 16:04:04
User entered 'No (N)'	System	01 Sep 2020 16:04:04

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:03:20', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de59fa73-c7b1-4f6f-82f7-919a10887f57'	System	01 Sep 2020 16:04:04
User entered 'No (N)'	System	01 Sep 2020 16:04:04

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:03:24', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de59fa73-c7b1-4f6f-82f7-919a10887f57'	System	01 Sep 2020 16:04:04
User entered 'None (1)'	System	01 Sep 2020 16:04:04

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:03:32', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de59fa73-c7b1-4f6f-82f7-919a10887f57' User entered '01 Sep 2020 12:03'	System	01 Sep 2020 16:04:04
	System	01 Sep 2020 16:04:04

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 7'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:15', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '0fde590a-f66a-4e31-b0df-1a38fe5069c2'	System	02 Sep 2020 16:04:51
User entered 'None (1)'	System	02 Sep 2020 16:04:51

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:18', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '0fde590a-f66a-4e31-b0df-1a38fe5069c2'	System	02 Sep 2020 16:04:51
User entered 'No (N)'	System	02 Sep 2020 16:04:51

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:21', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '0fde590a-f66a-4e31-b0df-1a38fe5069c2' User entered 'No (N)'	System	02 Sep 2020 16:04:51
	System	02 Sep 2020 16:04:51

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:25', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '0fde590a-f66a-4e31-b0df-1a38fe5069c2'	System	02 Sep 2020 16:04:51
User entered 'None (1)'	System	02 Sep 2020 16:04:51

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:30', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '0fde590a-f66a-4e31-b0df-1a38fe5069c2' User entered '02 Sep 2020 12:04'	System	02 Sep 2020 16:04:51
	System	02 Sep 2020 16:04:51

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:54:53', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fb4503ca-55b2-4e06-a214-8c9eaf2bd5ab' User entered 'None (0)'	System	27 Aug 2020 15:55:56
	System	27 Aug 2020 15:55:56

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:54:58', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fb4503ca-55b2-4e06-a214-8c9eaf2bd5ab' User entered 'None (0)'	System	27 Aug 2020 15:55:56
	System	27 Aug 2020 15:55:56

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:55:05', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fb4503ca-55b2-4e06-a214-8c9eaf2bd5ab' User entered 'None (0)'	System	27 Aug 2020 15:55:56
	System	27 Aug 2020 15:55:56

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:55:27', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fb4503ca-55b2-4e06-a214-8c9eaf2bd5ab' User entered 'None (0)'	System	27 Aug 2020 15:55:56
	System	27 Aug 2020 15:55:56

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:55:30', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fb4503ca-55b2-4e06-a214-8c9eaf2bd5ab' User entered 'None (0)'	System	27 Aug 2020 15:55:56
	System	27 Aug 2020 15:55:56

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:55:33', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fb4503ca-55b2-4e06-a214-8c9eaf2bd5ab' User entered 'None (0)'	System	27 Aug 2020 15:55:56
	System	27 Aug 2020 15:55:56

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:55:44', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fb4503ca-55b2-4e06-a214-8c9eaf2bd5ab'	System	27 Aug 2020 15:55:56
User entered 'No (N)'	System	27 Aug 2020 15:55:56

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T11:55:53', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fb4503ca-55b2-4e06-a214-8c9eaf2bd5ab' User entered '27 Aug 2020 11:55'	System	27 Aug 2020 15:55:56
	System	27 Aug 2020 15:55:56

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '27 Aug 2020 11:36'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '27 Aug 2020 14:06'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:23', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'dbdd2c88-66e5-4527-b854-82d08f4baba6' User entered 'None (0)'	System	28 Aug 2020 00:30:13
	System	28 Aug 2020 00:30:13

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:38', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'dbdd2c88-66e5-4527-b854-82d08f4baba6' User entered 'None (0)'	System	28 Aug 2020 00:30:13
	System	28 Aug 2020 00:30:13

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:41', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'dbdd2c88-66e5-4527-b854-82d08f4baba6' User entered 'None (0)'	System	28 Aug 2020 00:30:13
	System	28 Aug 2020 00:30:13

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:46', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'dbdd2c88-66e5-4527-b854-82d08f4baba6' User entered 'None (0)'	System	28 Aug 2020 00:30:13
	System	28 Aug 2020 00:30:13

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:49', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'dbdd2c88-66e5-4527-b854-82d08f4baba6' User entered 'None (0)'	System	28 Aug 2020 00:30:13
	System	28 Aug 2020 00:30:13

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:52', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'dbdd2c88-66e5-4527-b854-82d08f4baba6' User entered 'None (0)'	System	28 Aug 2020 00:30:13
	System	28 Aug 2020 00:30:13

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:29:56', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'dbdd2c88-66e5-4527-b854-82d08f4baba6' User entered 'No (N)'	System	28 Aug 2020 00:30:13
	System	28 Aug 2020 00:30:13

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-27T20:30:10', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'dbdd2c88-66e5-4527-b854-82d08f4baba6' User entered '27 Aug 2020 20:30'	System	28 Aug 2020 00:30:13
	System	28 Aug 2020 00:30:13

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '27 Aug 2020 15:01'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 2'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:01:45', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '3aa31ad4-56c9-4e15-a3fd-e4eaf65112cd'	System	28 Aug 2020 16:04:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	28 Aug 2020 16:04:45

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:01:51', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '3aa31ad4-56c9-4e15-a3fd-e4eaf65112cd'	System	28 Aug 2020 16:04:45
User entered 'Some interference with activity (2)'	System	28 Aug 2020 16:04:45

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:01:58', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '3aa31ad4-56c9-4e15-a3fd-e4eaf65112cd'	System	28 Aug 2020 16:04:45
User entered 'Some interference with activity (2)'	System	28 Aug 2020 16:04:45

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:02:23', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '3aa31ad4-56c9-4e15-a3fd-e4eaf65112cd'	System	28 Aug 2020 16:04:45
User entered 'Some interference with activity (2)'	System	28 Aug 2020 16:04:45

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:02:35', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '3aa31ad4-56c9-4e15-a3fd-e4eaf65112cd'	System	28 Aug 2020 16:04:45
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Aug 2020 16:04:45

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:02:39', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '3aa31ad4-56c9-4e15-a3fd-e4eaf65112cd' User entered 'None (0)'	System	28 Aug 2020 16:04:45
	System	28 Aug 2020 16:04:45

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:02:44', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '3aa31ad4-56c9-4e15-a3fd-e4eaf65112cd' User entered 'No (N)'	System	28 Aug 2020 16:04:45
	System	28 Aug 2020 16:04:45

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-28T12:03:33', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '3aa31ad4-56c9-4e15-a3fd-e4eaf65112cd' User entered '28 Aug 2020 12:03'	System	28 Aug 2020 16:04:45
	System	28 Aug 2020 16:04:45

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 3'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:51:56', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c6a85b56-331c-447d-bb5b-a4e23d5cadcf'	System	29 Aug 2020 16:52:42
User entered 'No interference with activity (1)'	System	29 Aug 2020 16:52:42

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:52:01', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c6a85b56-331c-447d-bb5b-a4e23d5cadcf' User entered 'None (0)'	System	29 Aug 2020 16:52:42
	System	29 Aug 2020 16:52:42

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:52:04', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c6a85b56-331c-447d-bb5b-a4e23d5cadcf' User entered 'None (0)'	System	29 Aug 2020 16:52:42
	System	29 Aug 2020 16:52:42

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:52:20', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c6a85b56-331c-447d-bb5b-a4e23d5cadcf' User entered 'None (0)'	System	29 Aug 2020 16:52:42
	System	29 Aug 2020 16:52:42

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:52:24', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c6a85b56-331c-447d-bb5b-a4e23d5cadcf' User entered 'None (0)'	System	29 Aug 2020 16:52:42
	System	29 Aug 2020 16:52:42

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:52:27', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c6a85b56-331c-447d-bb5b-a4e23d5cadcf' User entered 'None (0)'	System	29 Aug 2020 16:52:42
	System	29 Aug 2020 16:52:42

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:52:31', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c6a85b56-331c-447d-bb5b-a4e23d5cadcf' User entered 'No (N)'	System	29 Aug 2020 16:52:42
	System	29 Aug 2020 16:52:42

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-29T12:52:39', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c6a85b56-331c-447d-bb5b-a4e23d5cadcf' User entered '29 Aug 2020 12:52'	System	29 Aug 2020 16:52:42
	System	29 Aug 2020 16:52:42

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 4'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:02:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de241043-3fa0-4f59-bb6a-111c6689da9a' User entered 'None (0)'	System	30 Aug 2020 16:03:14
	System	30 Aug 2020 16:03:14

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:02:05', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de241043-3fa0-4f59-bb6a-111c6689da9a' User entered 'None (0)'	System	30 Aug 2020 16:03:14
	System	30 Aug 2020 16:03:14

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:02:08', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de241043-3fa0-4f59-bb6a-111c6689da9a' User entered 'None (0)'	System	30 Aug 2020 16:03:14
	System	30 Aug 2020 16:03:14

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:02:12', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de241043-3fa0-4f59-bb6a-111c6689da9a' User entered 'None (0)'	System	30 Aug 2020 16:03:14
	System	30 Aug 2020 16:03:14

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:02:22', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de241043-3fa0-4f59-bb6a-111c6689da9a' User entered 'None (0)'	System	30 Aug 2020 16:03:14
	System	30 Aug 2020 16:03:14

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:02:25', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de241043-3fa0-4f59-bb6a-111c6689da9a' User entered 'None (0)'	System	30 Aug 2020 16:03:14
	System	30 Aug 2020 16:03:14

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:02:31', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de241043-3fa0-4f59-bb6a-111c6689da9a' User entered 'No (N)'	System	30 Aug 2020 16:03:14
	System	30 Aug 2020 16:03:14

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-30T12:02:40', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'de241043-3fa0-4f59-bb6a-111c6689da9a' User entered '30 Aug 2020 12:02'	System	30 Aug 2020 16:03:14
	System	30 Aug 2020 16:03:14

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 5'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:41', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '348921ff-d564-4e26-ad53-558292e2ad75'	System	01 Sep 2020 01:37:28
User entered 'None (0)'	System	01 Sep 2020 01:37:28

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:48', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '348921ff-d564-4e26-ad53-558292e2ad75' User entered 'None (0)'	System	01 Sep 2020 01:37:28
	System	01 Sep 2020 01:37:28

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:52', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '348921ff-d564-4e26-ad53-558292e2ad75' User entered 'None (0)'	System	01 Sep 2020 01:37:28
	System	01 Sep 2020 01:37:28

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:36:58', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '348921ff-d564-4e26-ad53-558292e2ad75' User entered 'None (0)'	System	01 Sep 2020 01:37:28
	System	01 Sep 2020 01:37:28

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:37:03', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '348921ff-d564-4e26-ad53-558292e2ad75' User entered 'None (0)'	System	01 Sep 2020 01:37:28
	System	01 Sep 2020 01:37:28

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:37:14', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '348921ff-d564-4e26-ad53-558292e2ad75' User entered 'None (0)'	System	01 Sep 2020 01:37:28
	System	01 Sep 2020 01:37:28

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:37:18', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '348921ff-d564-4e26-ad53-558292e2ad75'	System	01 Sep 2020 01:37:28
User entered 'No (N)'	System	01 Sep 2020 01:37:28

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-08-31T21:37:26', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '348921ff-d564-4e26-ad53-558292e2ad75'	System	01 Sep 2020 01:37:28
User entered '31 Aug 2020 21:37'	System	01 Sep 2020 01:37:28

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 6'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:03:39', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd9905f35-a429-466f-bb1c-b2926aeb6936' User entered 'None (0)'	System	01 Sep 2020 16:04:49
	System	01 Sep 2020 16:04:49

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:03:43', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd9905f35-a429-466f-bb1c-b2926aeb6936' User entered 'None (0)'	System	01 Sep 2020 16:04:49
	System	01 Sep 2020 16:04:49

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:04:05', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd9905f35-a429-466f-bb1c-b2926aeb6936' User entered 'None (0)'	System	01 Sep 2020 16:04:49
	System	01 Sep 2020 16:04:49

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:04:08', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd9905f35-a429-466f-bb1c-b2926aeb6936' User entered 'None (0)'	System	01 Sep 2020 16:04:49
	System	01 Sep 2020 16:04:49

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:04:27', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd9905f35-a429-466f-bb1c-b2926aeb6936'	System	01 Sep 2020 16:04:49
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Sep 2020 16:04:49

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:04:31', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd9905f35-a429-466f-bb1c-b2926aeb6936' User entered 'None (0)'	System	01 Sep 2020 16:04:49
	System	01 Sep 2020 16:04:49

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:04:36', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd9905f35-a429-466f-bb1c-b2926aeb6936' User entered 'No (N)'	System	01 Sep 2020 16:04:49
	System	01 Sep 2020 16:04:49

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-01T12:04:45', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'd9905f35-a429-466f-bb1c-b2926aeb6936' User entered '01 Sep 2020 12:04'	System	01 Sep 2020 16:04:49
	System	01 Sep 2020 16:04:49

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 7'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:35', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '4bcaef26-1a7b-4862-9a60-1d4b04f9d74b' User entered 'None (0)'	System	02 Sep 2020 16:05:58
	System	02 Sep 2020 16:05:58

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:39', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '4bcaef26-1a7b-4862-9a60-1d4b04f9d74b' User entered 'None (0)'	System	02 Sep 2020 16:05:58
	System	02 Sep 2020 16:05:58

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:42', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '4bcaef26-1a7b-4862-9a60-1d4b04f9d74b' User entered 'None (0)'	System	02 Sep 2020 16:05:58
	System	02 Sep 2020 16:05:58

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:47', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '4bcaef26-1a7b-4862-9a60-1d4b04f9d74b' User entered 'None (0)'	System	02 Sep 2020 16:05:58
	System	02 Sep 2020 16:05:58

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:50', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '4bcaef26-1a7b-4862-9a60-1d4b04f9d74b' User entered 'None (0)'	System	02 Sep 2020 16:05:58
	System	02 Sep 2020 16:05:58

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:53', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '4bcaef26-1a7b-4862-9a60-1d4b04f9d74b' User entered 'None (0)'	System	02 Sep 2020 16:05:58
	System	02 Sep 2020 16:05:58

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:04:58', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '4bcaef26-1a7b-4862-9a60-1d4b04f9d74b' User entered 'No (N)'	System	02 Sep 2020 16:05:58
	System	02 Sep 2020 16:05:58

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-09-02T12:05:52', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '4bcaef26-1a7b-4862-9a60-1d4b04f9d74b' User entered '02 Sep 2020 12:05'	System	02 Sep 2020 16:05:58
	System	02 Sep 2020 16:05:58

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 15:46:10

US3532170

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:10:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Sep 2020 14:44:28

US3532170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	03 Sep 2020 22:55:38
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	03 Sep 2020 22:55:38
User entered '3 Sep 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	03 Sep 2020 22:55:38
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	02 Sep 2020 14:44:28
User entered '2 Sep 2020'	System	02 Sep 2020 14:44:28
	Lisa Macoy (b) (4)	02 Sep 2020 14:44:28
	(b) (4)	

US3532170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	02 Sep 2020 14:44:28

US3532170

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	02 Sep 2020 14:44:28

US3532170

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Sep 2020 22:55:46

US3532170

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'I'	System	03 Sep 2020 22:55:46

US3532170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	18 Sep 2020 14:54:52

US3532170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 06:03:43
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Subject is hospitalized ' (Site from System).	Lisa Macoy (b) (4) (b) (4)	18 Sep 2020 14:56:55
User entered '15 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4) (b) (4)	18 Sep 2020 14:56:26
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Sep 2020 14:54:52
User entered '18 Sep 2020'	Lisa Macoy (b) (4) (b) (4)	18 Sep 2020 14:54:52

US3532170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	18 Sep 2020 14:54:52

US3532170

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	18 Sep 2020 14:54:52

US3532170

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	18 Sep 2020 14:57:00

US3532170

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'I'	System	18 Sep 2020 14:57:00

US3532170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	18 Sep 2020 14:57:14

US3532170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '18 Sep 2020'	Lisa Macoy (b) (4)	18 Sep 2020 14:57:14

US3532170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	18 Sep 2020 14:57:14

US3532170

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered empty.	Lisa Macoy (b) (4)	18 Sep 2020 14:57:14

US3532170

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	18 Sep 2020 14:57:19

US3532170

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'I'	System	18 Sep 2020 14:57:19

US3532170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	16 Oct 2020 14:53:19

US3532170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	16 Oct 2020 14:53:19

US3532170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	16 Oct 2020 14:53:19

US3532170

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'VISIT2'	System	16 Oct 2020 14:53:19

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Macoy (b) (4) (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Macoy (b) (4) (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:49

US3532170

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	31 Jan 2021 20:03:56

US3532170

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:03:56

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Lisa Macoy (b) (4)	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:14

US3532170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	31 Jan 2021 20:04:24

US3532170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:24

US3532170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:24

US3532170

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:24

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:37

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lisa Macoy (b) (4) (b) (4)	31 Jan 2021 20:04:37

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	31 Jan 2021 20:04:37

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:37

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:37

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lisa Macoy (b) (4) (b) (4)	31 Jan 2021 20:04:37

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	31 Jan 2021 20:04:37

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:04:37

US3532170

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered empty.	System	31 Jan 2021 20:04:37

US3532170

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	16 Oct 2020 14:53:38

US3532170

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'I'	System	16 Oct 2020 14:53:38

US3532170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	27 Oct 2020 15:34:19
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	27 Oct 2020 15:33:58
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	27 Oct 2020 15:33:58
User entered 'Yes (Y)' reason for change: New Information	Lisa Macoy (b) (4)	27 Oct 2020 15:33:58
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	System	27 Oct 2020 15:32:49
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Oct 2020 15:32:49
	(b) (4)	16 Oct 2020 14:54:16

US3532170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered '4 Oct 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	27 Oct 2020 15:34:19
User entered empty; reason for change Data Entry Error	Lisa Macoy (b) (4)	27 Oct 2020 15:32:49
User entered '9 Oct 2020'	Lisa Macoy (b) (4)	16 Oct 2020 14:54:16

US3532170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	27 Oct 2020 15:32:57
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	16 Oct 2020 14:54:16

US3532170

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Unable to follow up due to SAE hospitalization	(b) (4)	
NO VACCINE 2 WILL BE GIVEN PER PI' reason	Lisa Macoy (b) (4)	27 Oct 2020 15:33:58
for change: New Information	(b) (4)	
User entered 'follow up from SAE.	Lisa Macoy (b) (4)	16 Oct 2020 14:54:16
NO Vaccine 2 will be given per PI'	(b) (4)	

US3532170

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:03:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	16 Oct 2020 14:54:23

US3532170

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'I'	System	16 Oct 2020 14:54:23

US3532170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 14:40:57

US3532170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '9 Oct 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	27 Oct 2020 15:34:42
User entered '19 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 14:40:57

US3532170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	19 Oct 2020 14:40:57

US3532170

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 14:40:57

US3532170

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 14:41:03

US3532170

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'I'	System	19 Oct 2020 14:41:03

US3532170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Oct 2020 15:34:55

US3532170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '19 Oct 2020'	Lisa Macoy (b) (4)	27 Oct 2020 15:34:55

US3532170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	27 Oct 2020 15:34:55

US3532170

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	27 Oct 2020 15:34:55

US3532170

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	27 Oct 2020 15:35:00

US3532170

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'I'	System	27 Oct 2020 15:35:00

US3532170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Oct 2020 18:04:51

US3532170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '28 Oct 2020'	Lisa Macoy (b) (4)	28 Oct 2020 18:04:51

US3532170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	28 Oct 2020 18:04:51

US3532170

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'VISIT3'	System	28 Oct 2020 18:04:51

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '28 Oct 2020'	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '14:01'	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered '28 Oct 2020 14:01'	System	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '97.6' F	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '82'	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'bpm'	System	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '20'	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'breaths/min'	System	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '102'	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'mmHg'	System	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '60'	Lisa Macoy (b) (4)	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'mmHg'	System	28 Oct 2020 18:06:38

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55

US3532170

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55

US3532170

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Oct 2020 18:06:46

US3532170

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered empty.	Lisa Macoy (b) (4)	28 Oct 2020 18:06:46

US3532170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Nov 2020 15:33:16

US3532170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '28 Oct 2020'	Lisa Macoy (b) (4)	12 Nov 2020 15:33:16

US3532170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered '14:17'	Lisa Macoy (b) (4)	12 Nov 2020 15:33:16

US3532170

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered '28 Oct 2020 14:17'	System	12 Nov 2020 15:33:16

US3532170

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:15:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Nov 2020 15:33:22

US3532170

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:46:55
User entered 'I'	System	12 Nov 2020 15:33:22

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 64'	System	27 Aug 2020 15:46:10

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-10-27T09:36:32', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '78627651-1cd4-48da-bc6f-d5671689802e' User entered 'Yes (Y)'	System	27 Oct 2020 13:37:50
	System	27 Oct 2020 13:37:50

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-10-27T09:36:45', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '78627651-1cd4-48da-bc6f-d5671689802e' User entered 'No (N)'	System	27 Oct 2020 13:37:50
	System	27 Oct 2020 13:37:50

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-10-27T09:36:51', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '78627651-1cd4-48da-bc6f-d5671689802e'	System	27 Oct 2020 13:37:50
User entered 'No (N)'	System	27 Oct 2020 13:37:50

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-10-27T09:36:59', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '78627651-1cd4-48da-bc6f-d5671689802e' User entered 'Yes (Y)'	System	27 Oct 2020 13:37:50
	System	27 Oct 2020 13:37:50

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Please 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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-10-27T09:37:15', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '78627651-1cd4-48da-bc6f-d5671689802e'	System	27 Oct 2020 13:37:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Oct 2020 13:37:50

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-10-27T09:37:41', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '78627651-1cd4-48da-bc6f-d5671689802e' User entered '27 Oct 2020 09:37:41'	System	27 Oct 2020 13:37:50
	System	27 Oct 2020 13:37:50

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 15:46:10

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 71'	System	27 Aug 2020 15:46:10

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-03T02:39:42', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'ab0036be-7072-472b-b9f1-a7c8fc5e76e0'	System	03 Nov 2020 07:40:13
User entered 'No (N)'	System	03 Nov 2020 07:40:13

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-03T02:39:49', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'ab0036be-7072-472b-b9f1-a7c8fc5e76e0'	System	03 Nov 2020 07:40:13
User entered 'No (N)'	System	03 Nov 2020 07:40:13

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-03T02:40:08', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'ab0036be-7072-472b-b9f1-a7c8fc5e76e0' User entered '03 Nov 2020 02:40:08'	System	03 Nov 2020 07:40:13
	System	03 Nov 2020 07:40:13

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 15:46:10

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered 'Day 78'	System	27 Aug 2020 15:46:10

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-13T18:51:56', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '6651ea9b-a814-4473-894e-07722ba9a7a0' User entered 'No (N)'	System	13 Nov 2020 23:52:16
	System	13 Nov 2020 23:52:16

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-13T18:52:03', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '6651ea9b-a814-4473-894e-07722ba9a7a0' User entered 'No (N)'	System	13 Nov 2020 23:52:16
	System	13 Nov 2020 23:52:16

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-13T18:52:14', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '6651ea9b-a814-4473-894e-07722ba9a7a0' User entered '13 Nov 2020 18:52:14'	System	13 Nov 2020 23:52:16
	System	13 Nov 2020 23:52:16

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 15:46:10

US3532170

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:32:53
Data entry locked.	System	27 Aug 2020 15:46:10
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 15:46:10

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-24T00:01:37', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c45bb5bd-ab64-496f-a35a-abd242b01a16'	System	24 Nov 2020 05:02:04
User entered 'No (N)'	System	24 Nov 2020 05:02:04

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-24T00:01:47', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c45bb5bd-ab64-496f-a35a-abd242b01a16'	System	24 Nov 2020 05:02:04
User entered 'No (N)'	System	24 Nov 2020 05:02:04

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-24T00:02:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c45bb5bd-ab64-496f-a35a-abd242b01a16'	System	24 Nov 2020 05:02:04
User entered '24 Nov 2020 00:02:00'	System	24 Nov 2020 05:02:04

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-30T12:00:45', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '872a0dd2-3fa5-4625-b7ae-624f1307a3fd' User entered 'No (N)'	System	30 Nov 2020 17:01:07

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-30T12:00:50', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '872a0dd2-3fa5-4625-b7ae-624f1307a3fd' User entered 'No (N)'	System	30 Nov 2020 17:01:07

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-11-30T12:00:56', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '872a0dd2-3fa5-4625-b7ae-624f1307a3fd' User entered '30 Nov 2020 12:00:56'	System	30 Nov 2020 17:01:07

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-12-05T02:32:09', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '1d6ed4a4-90cb-4b63-a57a-4890be75c357'	System	05 Dec 2020 07:32:43
User entered 'No (N)'	System	05 Dec 2020 07:32:43

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-12-05T02:32:15', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '1d6ed4a4-90cb-4b63-a57a-4890be75c357'	System	05 Dec 2020 07:32:43
User entered 'No (N)'	System	05 Dec 2020 07:32:43

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-12-05T02:32:41', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '1d6ed4a4-90cb-4b63-a57a-4890be75c357' User entered '05 Dec 2020 02:32:41'	System	05 Dec 2020 07:32:43
	System	05 Dec 2020 07:32:43

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-12-12T03:00:24', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b842df5b-2ab5-420e-83d2-41e4c099d547'	System	12 Dec 2020 08:00:49
User entered 'No (N)'	System	12 Dec 2020 08:00:49

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-12-12T03:00:27', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b842df5b-2ab5-420e-83d2-41e4c099d547'	System	12 Dec 2020 08:00:49
User entered 'No (N)'	System	12 Dec 2020 08:00:49

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-12-12T03:00:44', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b842df5b-2ab5-420e-83d2-41e4c099d547' User entered '12 Dec 2020 03:00:44'	System	12 Dec 2020 08:00:49
	System	12 Dec 2020 08:00:49

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-12-28T12:00:32', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'ca76b175-ce8e-4ad1-9036-a3065b9e4e6b' User entered 'No (N)'	System	28 Dec 2020 17:01:02
	System	28 Dec 2020 17:01:02

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-12-28T12:00:40', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'ca76b175-ce8e-4ad1-9036-a3065b9e4e6b' User entered 'No (N)'	System	28 Dec 2020 17:01:02
	System	28 Dec 2020 17:01:02

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2020-12-28T12:00:51', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'ca76b175-ce8e-4ad1-9036-a3065b9e4e6b' User entered '28 Dec 2020 12:00:51'	System	28 Dec 2020 17:01:02

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-02T12:28:16', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '286afff7-21cd-406f-be6d-6fa35b3c23c7'	System	02 Jan 2021 17:28:51
User entered 'No (N)'	System	02 Jan 2021 17:28:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-02T12:28:22', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '286afff7-21cd-406f-be6d-6fa35b3c23c7'	System	02 Jan 2021 17:28:51
User entered 'No (N)'	System	02 Jan 2021 17:28:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-02T12:28:48', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '286afff7-21cd-406f-be6d-6fa35b3c23c7'	System	02 Jan 2021 17:28:51
User entered '02 Jan 2021 12:28:48'	System	02 Jan 2021 17:28:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-11T12:13:36', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8bfcee5f-fa2f-41fc-acf3-c19746e3a4fe' User entered 'No (N)'	System	11 Jan 2021 17:14:01

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-11T12:13:40', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8bfcee5f-fa2f-41fc-acf3-c19746e3a4fe' User entered 'No (N)'	System	11 Jan 2021 17:14:01

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-11T12:13:55', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '8bfcee5f-fa2f-41fc-acf3-c19746e3a4fe' User entered '11 Jan 2021 12:13:55'	System	11 Jan 2021 17:14:01

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-18T15:19:10', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '98aa9b5d-2b13-4e73-a820-d9b15b64f466'	System	18 Jan 2021 20:19:32
User entered 'No (N)'	System	18 Jan 2021 20:19:32

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-18T15:19:17', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '98aa9b5d-2b13-4e73-a820-d9b15b64f466'	System	18 Jan 2021 20:19:32
User entered 'No (N)'	System	18 Jan 2021 20:19:32

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-18T15:19:30', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '98aa9b5d-2b13-4e73-a820-d9b15b64f466'	System	18 Jan 2021 20:19:32
User entered '18 Jan 2021 15:19:30'	System	18 Jan 2021 20:19:32

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-23T23:03:03', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '2df9c0eb-1c11-4749-8be3-e843e9845520'	System	24 Jan 2021 04:03:25
User entered 'No (N)'	System	24 Jan 2021 04:03:25

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-23T23:03:08', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '2df9c0eb-1c11-4749-8be3-e843e9845520'	System	24 Jan 2021 04:03:25
User entered 'No (N)'	System	24 Jan 2021 04:03:25

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-23T23:03:22', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '2df9c0eb-1c11-4749-8be3-e843e9845520' User entered '23 Jan 2021 23:03:22'	System	24 Jan 2021 04:03:25
	System	24 Jan 2021 04:03:25

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-30T01:21:07', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c3cf3f1f-f6de-4c33-bfb3-fdc052ba3771'	System	30 Jan 2021 06:21:33
User entered 'No (N)'	System	30 Jan 2021 06:21:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-30T01:21:15', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c3cf3f1f-f6de-4c33-bfb3-fdc052ba3771'	System	30 Jan 2021 06:21:33
User entered 'No (N)'	System	30 Jan 2021 06:21:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-01-30T01:21:30', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'c3cf3f1f-f6de-4c33-bfb3-fdc052ba3771' User entered '30 Jan 2021 01:21:30'	System	30 Jan 2021 06:21:33
	System	30 Jan 2021 06:21:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-06T06:00:06', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '68bc9d88-8205-48d0-8ad3-dce11afc4773'	System	06 Feb 2021 11:00:59
User entered 'No (N)'	System	06 Feb 2021 11:00:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-06T06:00:13', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '68bc9d88-8205-48d0-8ad3-dce11afc4773'	System	06 Feb 2021 11:00:59
User entered 'No (N)'	System	06 Feb 2021 11:00:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-06T06:00:55', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '68bc9d88-8205-48d0-8ad3-dce11afc4773' User entered '06 Feb 2021 06:00:55'	System	06 Feb 2021 11:00:59
	System	06 Feb 2021 11:00:59

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-13T09:48:26', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '291a5c4c-3739-46c0-86d4-1ec37f683efb' User entered 'No (N)'	System	13 Feb 2021 14:48:53
	System	13 Feb 2021 14:48:53

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-13T09:48:37', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '291a5c4c-3739-46c0-86d4-1ec37f683efb' User entered 'No (N)'	System	13 Feb 2021 14:48:53

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-13T09:48:50', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '291a5c4c-3739-46c0-86d4-1ec37f683efb' User entered '13 Feb 2021 09:48:50'	System	13 Feb 2021 14:48:53
	System	13 Feb 2021 14:48:53

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-21T23:09:02', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '94683cf6-7892-4ac1-8682-2525bc13adea' User entered 'Yes (Y)'	System	22 Feb 2021 04:09:51
	System	22 Feb 2021 04:09:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-21T23:05:19', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '94683cf6-7892-4ac1-8682-2525bc13adea' User entered 'No (N)'	System	22 Feb 2021 04:09:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-21T23:05:28', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '94683cf6-7892-4ac1-8682-2525bc13adea' User entered 'No (N)'	System	22 Feb 2021 04:09:51
	System	22 Feb 2021 04:09:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-21T23:05:35', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '94683cf6-7892-4ac1-8682-2525bc13adea' User entered 'Yes (Y)'	System	22 Feb 2021 04:09:51
	System	22 Feb 2021 04:09:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-21T23:06:16', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '94683cf6-7892-4ac1-8682-2525bc13adea'	System	22 Feb 2021 04:09:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Feb 2021 04:09:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-21T23:09:40', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '94683cf6-7892-4ac1-8682-2525bc13adea' User entered '21 Feb 2021 23:09:40'	System	22 Feb 2021 04:09:51
	System	22 Feb 2021 04:09:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-27T02:23:36-05:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'be47304b-2f38-4be3-9d60-13fb50819937' User entered 'No (N)'	System	27 Feb 2021 07:23:53

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-27T02:23:40-05:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'be47304b-2f38-4be3-9d60-13fb50819937' User entered 'No (N)'	System	27 Feb 2021 07:23:53

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-02-27T02:23:51-05:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'be47304b-2f38-4be3-9d60-13fb50819937' User entered '27 Feb 2021 07:23:51'	System	27 Feb 2021 07:23:53

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-07T23:03:27-05:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e566baff-397e-41bb-b5f5-6f712954b988'	System	08 Mar 2021 04:04:35
User entered 'No (N)'	System	08 Mar 2021 04:04:35

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-07T23:03:35-05:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e566baff-397e-41bb-b5f5-6f712954b988'	System	08 Mar 2021 04:04:35
User entered 'No (N)'	System	08 Mar 2021 04:04:35

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-07T23:03:45-05:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'e566baff-397e-41bb-b5f5-6f712954b988'	System	08 Mar 2021 04:04:35
User entered '07 Mar 2021 23:03:45'	System	08 Mar 2021 04:04:35

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-14T19:21:20-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'a0937971-b379-4942-934d-226f0269de9c'	System	14 Mar 2021 23:21:44
User entered 'No (N)'	System	14 Mar 2021 23:21:44

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-14T19:21:24-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'a0937971-b379-4942-934d-226f0269de9c'	System	14 Mar 2021 23:21:44
User entered 'No (N)'	System	14 Mar 2021 23:21:44

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-14T19:21:40-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'a0937971-b379-4942-934d-226f0269de9c'	System	14 Mar 2021 23:21:44
User entered '14 Mar 2021 19:21:40'	System	14 Mar 2021 23:21:44

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-20T00:52:40-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'ec7c0d3f-2f19-4c2a-ba49-75e7d8d32f90'	System	20 Mar 2021 04:53:10
User entered 'No (N)'	System	20 Mar 2021 04:53:10

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-20T00:52:49-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'ec7c0d3f-2f19-4c2a-ba49-75e7d8d32f90'	System	20 Mar 2021 04:53:10
User entered 'No (N)'	System	20 Mar 2021 04:53:10

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-20T00:53:06-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'ec7c0d3f-2f19-4c2a-ba49-75e7d8d32f90'	System	20 Mar 2021 04:53:10
User entered '20 Mar 2021 00:53:06'	System	20 Mar 2021 04:53:10

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-27T02:54:40-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fdeb12c4-257b-4fee-960e-cc178107420f' User entered 'No (N)'	System	27 Mar 2021 06:54:57
	System	27 Mar 2021 06:54:57

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-27T02:54:48-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fdeb12c4-257b-4fee-960e-cc178107420f' User entered 'No (N)'	System	27 Mar 2021 06:54:57
	System	27 Mar 2021 06:54:57

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-27T02:54:55-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'fdeb12c4-257b-4fee-960e-cc178107420f' User entered '27 Mar 2021 02:54:55'	System	27 Mar 2021 06:54:57
	System	27 Mar 2021 06:54:57

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-03T01:51:58-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '189319c2-51f9-4d66-95a8-7b0b94ab8631'	System	03 Apr 2021 06:02:55
User entered 'No (N)'	System	03 Apr 2021 06:02:55

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-03T01:52:15-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '189319c2-51f9-4d66-95a8-7b0b94ab8631'	System	03 Apr 2021 06:02:55
User entered 'No (N)'	System	03 Apr 2021 06:02:55

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-03T01:53:20-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '189319c2-51f9-4d66-95a8-7b0b94ab8631'	System	03 Apr 2021 06:02:55
User entered '03 Apr 2021 01:53:20'	System	03 Apr 2021 06:02:55

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-10T00:06:21-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '23299a42-8b87-462d-a2cf-395d3d183955'	System	10 Apr 2021 04:08:36
User entered 'No (N)'	System	10 Apr 2021 04:08:36

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-10T00:06:33-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '23299a42-8b87-462d-a2cf-395d3d183955'	System	10 Apr 2021 04:08:36
User entered 'No (N)'	System	10 Apr 2021 04:08:36

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-10T00:07:01-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '23299a42-8b87-462d-a2cf-395d3d183955'	System	10 Apr 2021 04:08:36
User entered '10 Apr 2021 00:07:01'	System	10 Apr 2021 04:08:36

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-19T20:17:18-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b48771a8-2d56-4c2c-a60a-8ded9c6e82a4'	System	20 Apr 2021 00:17:50
User entered 'No (N)'	System	20 Apr 2021 00:17:50

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-19T20:17:27-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b48771a8-2d56-4c2c-a60a-8ded9c6e82a4'	System	20 Apr 2021 00:17:50
User entered 'No (N)'	System	20 Apr 2021 00:17:50

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-19T20:17:46-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: 'b48771a8-2d56-4c2c-a60a-8ded9c6e82a4'	System	20 Apr 2021 00:17:50
User entered '19 Apr 2021 20:17:46'	System	20 Apr 2021 00:17:50

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-25T21:02:08-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '6fc6b7bb-ea8f-4c2d-b46b-f9027b1c7c6a'	System	26 Apr 2021 01:07:51
User entered 'No (N)'	System	26 Apr 2021 01:07:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

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 (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-25T21:03:01-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '6fc6b7bb-ea8f-4c2d-b46b-f9027b1c7c6a'	System	26 Apr 2021 01:07:51
User entered 'No (N)'	System	26 Apr 2021 01:07:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-04-25T21:03:13-04:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '6fc6b7bb-ea8f-4c2d-b46b-f9027b1c7c6a'	System	26 Apr 2021 01:07:51
User entered '25 Apr 2021 21:03:13'	System	26 Apr 2021 01:07:51

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 18:51:33

US3532170

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:51:33
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 18:51:33

US3532170

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:10:48

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)	24 Apr 2021 10:10:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-10T15:51:30-05:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '08ca6c83-2928-4d0c-9751-6ae0c0e17b66'	System	10 Mar 2021 20:51:42
User entered 'No (N)'	System	10 Mar 2021 20:51:42

US3532170

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:10:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:10:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AB212D8D-D967-4B21-BA80-DD12D3D88138)', Time: '2021-03-10T15:51:40-05:00', User OID: 'PatientReportedOutcome (US3532170)', ODM File OID: '08ca6c83-2928-4d0c-9751-6ae0c0e17b66'	System	10 Mar 2021 20:51:42
User entered '10 Mar 2021 15:51:40'	System	10 Mar 2021 20:51:42

US3532170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:40:28
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	13 Nov 2020 19:21:24

US3532170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:40:28
User entered '16 Nov 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Nov 2020 17:06:41
User entered '13 Nov 2020'	Lisa Macoy (b) (4)	13 Nov 2020 19:21:24

US3532170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:40:28
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	13 Nov 2020 19:21:24

US3532170

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:40:28
User entered empty.	Lisa Macoy (b) (4)	13 Nov 2020 19:21:24

US3532170

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:40:28
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	13 Nov 2020 19:21:30

US3532170

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:41:19
User entered 'I'	System	13 Nov 2020 19:21:30

US3532170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	22 Dec 2020 17:56:15

US3532170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '22 Dec 2020'	Lisa Macoy (b) (4)	22 Dec 2020 17:56:15

US3532170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	22 Dec 2020 17:56:15

US3532170

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	22 Dec 2020 17:56:15

US3532170

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	22 Dec 2020 17:56:20

US3532170

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered 'I'	System	22 Dec 2020 17:56:20

US3532170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Jan 2021 14:26:54

US3532170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '19 Jan 2021'	Lisa Macoy (b) (4)	19 Jan 2021 14:26:54

US3532170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	19 Jan 2021 14:26:54

US3532170

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Jan 2021 14:26:54

US3532170

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Jan 2021 14:27:01

US3532170

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered 'I'	System	19 Jan 2021 14:27:01

US3532170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	24 Feb 2021 19:23:45

US3532170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '19 Feb 2021'	Lisa Macoy (b) (4)	24 Feb 2021 19:23:45

US3532170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	24 Feb 2021 19:23:45

US3532170

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	24 Feb 2021 19:23:45

US3532170

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	24 Feb 2021 19:23:50

US3532170

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered 'I'	System	24 Feb 2021 19:23:50

US3532170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Mar 2021 17:23:38

US3532170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered '10 Mar 2021'	Lisa Macoy (b) (4)	10 Mar 2021 17:23:38

US3532170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[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 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	10 Mar 2021 17:23:38

US3532170

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered 'VISIT4'	System	10 Mar 2021 17:23:38

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered 'No (N)'	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered empty.	System	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered empty.	System	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered empty.	System	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered empty.	System	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered empty.	System	01 Apr 2021 18:43:15

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32

US3532170

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32

US3532170

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User closed query 'Per CDM: Visit 4 Day 209 and OL- Day29 are both dated 10March2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 05:20:44
Query 'Per CDM: Visit 4 Day 209 and OL- Day29 are both dated 10March2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 18:03:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 18:02:58
User opened query 'Per CDM: Visit 4 Day 209 and OL- Day29 are both dated 10March2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 04:52:15
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 17:23:42

US3532170

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:01:09
User entered '10 Mar 2021' reason for change: Data Entry Error	Lisa Macoy (b) (4)	26 Mar 2021 18:02:58
User entered empty.	Lisa Macoy (b) (4)	10 Mar 2021 17:23:42

US3532170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Mar 2021 17:56:07

US3532170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '10 Mar 2021'	Lisa Macoy (b) (4)	10 Mar 2021 17:56:07

US3532170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '11:40'	Lisa Macoy (b) (4)	10 Mar 2021 17:56:07

US3532170

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered '10 Mar 2021 11:40'	System	10 Mar 2021 17:56:07

US3532170

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Mar 2021 17:24:06

US3532170

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:42:32
User entered 'I'	System	10 Mar 2021 17:24:06

US3532170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	22 Apr 2021 14:55:09
	(b) (4)	

US3532170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered '22 Apr 2021'	Lisa Macoy (b) (4)	22 Apr 2021 14:55:09
	(b) (4)	

US3532170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	22 Apr 2021 14:55:09

US3532170

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	22 Apr 2021 14:55:09
	(b) (4)	

US3532170

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	22 Apr 2021 15:17:41
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	22 Apr 2021 14:55:15

US3532170

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 14:55:15

US3532170

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

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 19:45:06

US3532170

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

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Feb 2021'	Lisa Macoy (b) (4)	02 Feb 2021 19:45:06

US3532170

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

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	02 Feb 2021 19:45:06

US3532170

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

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 19:45:06

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Feb 2021'	Lisa Macoy (b) (4)	02 Feb 2021 19:47:17

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:04:08

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 19:47:17

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:04:08

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Feb 2021'	Lisa Macoy (b) (4)	02 Feb 2021 19:47:17

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Placebo (Placebo)'	Lisa Macoy (b) (4)	02 Feb 2021 19:47:17

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Placebo (Placebo)'	Lisa Macoy (b) (4)	02 Feb 2021 19:47:17

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Not Administered (NA)'	Lisa Macoy (b) (4)	02 Feb 2021 19:47:17

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 19:47:17

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'I'	System	02 Feb 2021 19:47:17

US3532170

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

Form: Unblinding

Generated On: 10 Jun 2021 08:10:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'I'	System	02 Feb 2021 19:47:17

US3532170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered empty.	System	02 Feb 2021 20:10:03
DataPoint set to visible.	System	02 Feb 2021 19:47:17

US3532170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered empty.	System	02 Feb 2021 20:10:03
DataPoint set to visible.	System	02 Feb 2021 19:47:17

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Feb 2021'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '13:30'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered '2 Feb 2021 13:30'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '98.5' F	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '84'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'bpm'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '18'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'breaths/min'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '132'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mmHg'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '82'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mmHg'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered empty.	System	02 Feb 2021 20:10:03
DataPoint set to visible.	System	02 Feb 2021 19:47:17

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Feb 2021'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '15:05'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered '2 Feb 2021 15:05'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '98.2' F	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '76'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'bpm'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '18'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'breaths/min'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '124'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mmHg'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '77'	Lisa Macoy (b) (4)	02 Feb 2021 20:10:03

US3532170

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mmHg'	System	02 Feb 2021 20:10:03

US3532170

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 19:48:01

US3532170

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Feb 2021'	Lisa Macoy (b) (4)	02 Feb 2021 19:48:01

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 19:49:16

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 19:49:16

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 19:49:16

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mRNA-1273'	System	02 Feb 2021 19:49:16
DataPoint set to visible.	System	02 Feb 2021 19:47:17

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Feb 2021'	Lisa Macoy (b) (4)	02 Feb 2021 19:49:16

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '14:31'	Lisa Macoy (b) (4)	02 Feb 2021 19:49:16

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered '2 Feb 2021 14:31'	System	02 Feb 2021 19:49:16

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Right Arm (RIGHT ARM)'	Lisa Macoy (b) (4)	02 Feb 2021 19:49:16

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'ONCE'	System	02 Feb 2021 19:49:16

US3532170

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

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 19:49:16

US3532170

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 19:49:56

US3532170

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Feb 2021'	Lisa Macoy (b) (4)	02 Feb 2021 19:49:56

US3532170

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '14:06'	Lisa Macoy (b) (4)	02 Feb 2021 19:49:56

US3532170

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered '2 Feb 2021 14:06'	System	02 Feb 2021 19:49:56

US3532170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 19:50:13

US3532170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Feb 2021'	Lisa Macoy (b) (4)	02 Feb 2021 19:50:13

US3532170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '13:55'	Lisa Macoy (b) (4)	02 Feb 2021 19:50:13

US3532170

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered '2 Feb 2021 13:55'	System	02 Feb 2021 19:50:13

US3532170

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

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 19:50:27

US3532170

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

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'I'	System	02 Feb 2021 19:50:27

US3532170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	09 Feb 2021 14:41:43

US3532170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '9 Feb 2021'	Lisa Macoy (b) (4)	09 Feb 2021 14:41:43

US3532170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	09 Feb 2021 14:41:43

US3532170

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	09 Feb 2021 14:41:43

US3532170

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	09 Feb 2021 14:41:47

US3532170

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'I'	System	09 Feb 2021 14:41:47

US3532170

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'I'	System	09 Feb 2021 14:41:47
DataPoint set to visible.	System	09 Feb 2021 14:41:47

US3532170

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Mar 2021 17:24:24

US3532170

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '10 Mar 2021'	Lisa Macoy (b) (4)	10 Mar 2021 17:24:24

US3532170

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	10 Mar 2021 17:24:24

US3532170

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'OLD29'	System	10 Mar 2021 17:24:24

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '10 Mar 2021'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '11:18'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered '10 Mar 2021 11:18'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '96.9' F	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '65'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'bpm'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '18'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'breaths/min'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '112'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mmHg'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '69'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mmHg'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '10 Mar 2021'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12:39'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered '10 Mar 2021 12:39'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '98.9' F	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '62'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'bpm'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '18'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'breaths/min'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '115'	Lisa Macoy (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mmHg'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 04:26:22
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 17:40:37
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		10 Mar 2021 17:40:20
User entered '56'	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mmHg'	System	10 Mar 2021 17:40:20

US3532170

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Mar 2021 17:24:47

US3532170

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '10 Mar 2021'	Lisa Macoy (b) (4)	10 Mar 2021 17:24:47

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Mar 2021 17:25:23

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	10 Mar 2021 17:25:23

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	10 Mar 2021 17:25:23

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'mRNA-1273'	System	10 Mar 2021 17:25:23
DataPoint set to visible.	System	09 Feb 2021 14:41:47

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '10 Mar 2021'	Lisa Macoy (b) (4)	10 Mar 2021 17:25:23

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12:05'	Lisa Macoy (b) (4)	10 Mar 2021 17:25:23

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered '10 Mar 2021 12:05'	System	10 Mar 2021 17:25:23

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Right Arm (RIGHT ARM)'	Lisa Macoy (b) (4)	10 Mar 2021 17:25:23

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'ONCE'	System	10 Mar 2021 17:25:23

US3532170

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 17:25:23

US3532170

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Mar 2021 17:25:32

US3532170

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'I'	System	10 Mar 2021 17:25:32

US3532170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	18 Mar 2021 17:26:15

US3532170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '18 Mar 2021'	Lisa Macoy (b) (4)	18 Mar 2021 17:26:15

US3532170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	18 Mar 2021 17:26:15

US3532170

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	18 Mar 2021 17:26:15

US3532170

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	18 Mar 2021 17:26:21

US3532170

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:35
User entered 'I'	System	18 Mar 2021 17:26:21

US3532170

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	08 Apr 2021 16:16:12
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '8 Apr 2021'	Cindy Lubbers (b) (4)	08 Apr 2021 16:16:12
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	08 Apr 2021 16:16:12
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	08 Apr 2021 16:16:12

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '8 Apr 2021'	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '11:28'	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User entered '8 Apr 2021 11:28'	System	08 Apr 2021 16:17:31

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '98.7' F	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Oral (Oral)'	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '69'	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Apr 2021 16:17:31

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '18'	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Apr 2021 16:17:31

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '118'	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 16:17:31

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '76'	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:31
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 16:17:31

US3532170

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:37
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	08 Apr 2021 16:17:37
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	08 Apr 2021 16:18:10
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '8 Apr 2021'	Cindy Lubbers (b) (4)	08 Apr 2021 16:18:10
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '11:28'	Cindy Lubbers (b) (4)	08 Apr 2021 16:18:10
	(b) (4)	

US3532170

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User entered '8 Apr 2021 11:28'	System	08 Apr 2021 16:18:10

US3532170

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:10:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:49
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:13:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:33:52
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	15 Sep 2020 19:31:37

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:39:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:29:32
User entered	System	16 Sep 2020 13:29:09
'USA-US077-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	16 Sep 2020 13:29:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'please add AE Wheezing 14-18 Sep 20' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 01:49:49
Query 'please add AE Wheezing 14-18 Sep 20' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	16 Apr 2021 20:27:07
User opened query 'please add AE Wheezing 14-18 Sep 20' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 19:43:53
DataPoint Verified.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 19:31:13
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Acute myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4)	16 Oct 2020 19:20:19
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Oct 2020 19:20:19
	(b) (4)	
User closed query 'PV Query: The case narrative states the subject suffered from an "acute" MI. Please assess if the event term should be updated to Acute Myocardial Infarction and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 19:18:12
Data point term sent to Coder	System	16 Oct 2020 14:56:48
Query 'PV Query: The case narrative states the subject suffered from an "acute" MI. Please assess if the event term should be updated to Acute Myocardial Infarction and update as applicable.'	Lisa Macoy (b) (4)	16 Oct 2020 14:56:03
answered with 'UPDATED' (Site from Safety).	(b) (4)	
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Oct 2020 14:55:54
	(b) (4)	
Coding entries removed.	Lisa Macoy (b) (4)	16 Oct 2020 14:55:54
	(b) (4)	
User entered 'ACUTE MYOCARDIAL INFARTION' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Oct 2020 14:55:54
	(b) (4)	
User opened query 'PV Query: The case narrative states the subject suffered from an "acute" MI. Please assess if the event term should be updated to Acute Myocardial Infarction and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 14:06:18
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:39:22

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:51:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:51:07
Data point term sent to Coder	System	15 Sep 2020 19:38:23
User entered 'myocardial infarction'	Lisa Macoy (b) (4) (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:40:40
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:40:14
User entered 'No (N)'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:40:11
User entered 'No (N)'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:03
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 14:26:55
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 14:26:55
User entered '07 Sep 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Apr 2021 14:26:55
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:40:49
User entered '06 Sep 2020'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
DataPoint Un-verified.	Lisa Macoy (b) (4)	19 Oct 2020 14:56:31
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	19 Oct 2020 14:56:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:40:58
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 15:44:32
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	19 Oct 2020 14:56:39
	(b) (4)	
User entered '6 Oct 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	19 Oct 2020 14:56:31
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 14:04:00
User entered empty.	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
Query 'PV Query: The event intensity is "Grade 4" for this event of Myocardial Infarction. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:19:00
User opened query 'PV Query: The event intensity is "Grade 4" for this event of Myocardial Infarction. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 14:05:22
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:41:06
User entered 'Grade 4 (Grade 4)'	Lisa Macoy (b) (4) (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:41:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:41:14
User entered '0'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:41:16
User entered '0'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:41:17
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:27:03
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'still hospitalized' (Site from System).	Lisa Macoy (b) (4)	15 Sep 2020 19:38:55
	(b) (4)	
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	15 Sep 2020 19:38:09
User entered 'I'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:20
User closed query 'please review Hospital Admission Date with discharge summary' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:09:17
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
Query 'please review Hospital Admission Date with discharge summary' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	16 Apr 2021 13:35:59
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 13:35:32
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 13:35:32
User entered '07 Sep 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Apr 2021 13:35:32
User opened query 'please review Hospital Admission Date with discharge summary' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 14:44:53
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:41:32
User entered '06 Sep 2020'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 12:08:00
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	19 Oct 2020 14:56:44
	(b) (4)	
User entered '6 Oct 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	19 Oct 2020 14:56:31
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 14:03:40
User entered empty.	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:41:36
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '9'	Lisa Macoy (b) (4) (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:45:42
User entered '0'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:45:43
User entered '0'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:45:45
User entered '0'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:43:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 19:43:01
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Per CDM: Reason for Dosing discontinuation is SAE on the Dosing discontinuation form, however the Action with Investigational product is not Investigational product withdrawn. Please reconcile and update data accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:12:29
Query 'Per CDM: Reason for Dosing discontinuation is SAE on the Dosing discontinuation form, however the Action with Investigational product is not Investigational product withdrawn. Please reconcile and update data accordingly, else clarify.' answered with 'updated' (Site from DM).	Kathy Stephens (b) (4)	07 Nov 2020 20:54:24
	(b) (4)	
DataPoint Un-verified.	Kathy Stephens (b) (4)	07 Nov 2020 20:54:15
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Kathy Stephens (b) (4)	07 Nov 2020 20:54:15
	(b) (4)	
User opened query 'Per CDM: Reason for Dosing discontinuation is SAE on the Dosing discontinuation form, however the Action with Investigational product is not Investigational product withdrawn. Please reconcile and update data accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 09:27:55
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:43:04
User entered 'None (NONE)'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Please provide source for Con Meds and record in subjects source binder.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 17:25:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:01:28
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4)	20 Oct 2020 17:44:34
Query 'Please provide source for Con Meds and record in subjects source binder.' answered with 'updated' (Site from CRA).	(b) (4)	
	Lisa Macoy (b) (4)	20 Oct 2020 17:44:27
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:54:12
User opened query 'Please provide source for Con Meds and record in subjects source binder.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 19:44:32
User entered 'I'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Please provide source for Con procedures and record in subjects source binder' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 17:25:28
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:11:32
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4)	19 Oct 2020 19:40:11
	(b) (4)	
Query 'Please provide source for Con procedures and record in subjects source binder' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	19 Oct 2020 19:40:06
	(b) (4)	
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:54:16
User opened query 'Please provide source for Con procedures and record in subjects source binder' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 19:45:04
User entered '1'	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 01:50:26
User closed query 'please check with source if should be Resolved with Sequelae and specify (in field below)' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 01:50:01
Query 'please check with source if should be Resolved with Sequelae and specify (in field below)' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	16 Apr 2021 20:45:31
DataPoint Un-verified.	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 20:45:26
Signature has been broken.	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 20:45:26
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	(b) (4)	
User opened query 'please check with source if should be Resolved with Sequelae and specify (in field below)' (Site from CRA).	Lisa Macoy (b) (4)	16 Apr 2021 20:45:26
User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 19:12:00
DataPoint Verified.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 12:08:07
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	19 Oct 2020 14:56:58
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Lisa Macoy (b) (4)	19 Oct 2020 14:56:31
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 14:04:15

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lisa Macoy (b) (4) (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 01:50:14
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 20:45:26
	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 20:45:26
	(b) (4)	
User entered 'ventricular fibrillation-intermediate, anxiety, wheezing' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	16 Apr 2021 20:45:26
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	15 Sep 2020 19:38:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 13:35:53
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 13:35:53
User entered 'SUBJECT REPORTED ON 15SEP 202 SUFFERING ACUTE MI ON 07SEP2020 AND HAVING EMERGENCY BYPASS SURGERY. HISTORY OF HYPERTENSION, TYPE II DIABETES AND HYPERLIPIDEMIA BUT UNAWARE OF ANY ACUTE RISK. PI: WOULD CONSIDER THIS UNRELATED TO VACCINE, INSTEAD RELATED TO HER UNDERLYING TYPE 2 DIABETES, HYPERLIPIDEMIA AND HYPERTENSION. TIMING IS AT 10 DAYS AFTER VACCINATION WHICH ALSO MAKES IT LESS LIKELY TO BE RELATED.' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Apr 2021 13:35:53
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
User closed query 'PV Query: It was reported that the subject had ventricular fibrillation while hospitalized. Does this meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 14:15:50
Query 'PV Query: It was reported that the subject had ventricular fibrillation while hospitalized. Does this meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If not, please state so.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	09 Nov 2020 14:09:59
User opened query 'PV Query: It was reported that the subject had ventricular fibrillation while hospitalized. Does this meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 23:09:50
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)	22 Oct 2020 19:05:06

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:05:01
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)	21 Oct 2020 15:44:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'working on dedicating records now ' (Site from Safety).	Lisa Macoy (b) (4)	21 Oct 2020 12:50:37
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 'working on dedicating records now will send by end of day' (Site from Safety).	Lisa Macoy (b) (4)	21 Oct 2020 12:50:31
Query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 21:17:31
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'none' (Site from Safety).	Lisa Macoy (b) (4)	20 Oct 2020 18:39:29
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 Sep 2020 14:05:02

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 14:04:51
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 Sep 2020 14:04:30
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)	25 Sep 2020 14:03:27
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:45:26
User entered 'Subject reported on 15Sep 202 suffering acute MI on 06Sep2020 and having emergency bypass surgery. History of hypertension, Type II diabetes and hyperlipidemia but unaware of any acute risk. PI: would consider this UNrelated to vaccine, instead related to her underlying Type 2 Diabetes, hyperlipidemia and hypertension. Timing is at 10 days after vaccination which also makes it less likely to be related.'	Lisa Macoy (b) (4) (b) (4)	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 19:38:09

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Neurological and psychiatric procedural complications, PT: Procedural anxiety, LLT: Anxiety postoperative - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 03:09:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 03:09:44
Data point term sent to Coder	System	09 Nov 2020 14:09:55
User entered 'Anxiety post CABG'	Lisa Macoy (b) (4)	09 Nov 2020 14:09:06
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '06 Oct 2020'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:09:06
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'None (NONE)'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'I'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 14:09:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 14:09:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:17
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 14:09:06
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'subject placed on medication and dx with anxiety per Cardiac team after MI an post CABG'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 14:09:06

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 04:09:17
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'related to meds' (Site from DM).	Laila Hussaini (b) (4)	01 Dec 2020 18:06:04
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 07:58:03
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 14:24:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 14:24:32
Data point term sent to Coder	System	09 Nov 2020 14:23:09
User entered 'Nausea'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '12 Sep 2020'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User entered empty.	System	09 Nov 2020 14:22:32

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '09 Oct 2020'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User entered empty.	System	09 Nov 2020 14:22:32

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Grade 3/Severe (Grade 3/Severe)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'None (NONE)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 14:25:43
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 14:22:32
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4)	09 Nov 2020 14:25:43
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Severe nausea related to medication taken during hospitalization. Medications changed and subject able to stop Zofran'	Lisa Macoy (b) (4)	09 Nov 2020 14:22:32
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User entered '0'	System	09 Nov 2020 14:22:32

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44
User entered '1'	System	09 Nov 2020 14:22:32

US3532170

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:44

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Per MM: Please confirm this event does not meet the definition of an SAE. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 03:23:55
Query 'Per MM: Please confirm this event does not meet the definition of an SAE. ' answered with 'did not meet' (Site from DM).	Laila Hussaini (b) (4)	01 Dec 2020 18:06:21
User opened query 'Per MM: Please confirm this event does not meet the definition of an SAE. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 07:58:47
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular fibrillation, LLT: Ventricular fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 14:51:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 14:51:32
Data point term sent to Coder	System	10 Nov 2020 13:15:48
User entered 'ventricular fibrillation- intermediate'	Lisa Macoy (b) (4)	10 Nov 2020 13:15:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '08 Sep 2020'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Grade 3/Severe (Grade 3/Severe)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'None (NONE)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'I'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 13:15:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 13:15:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Lisa Macoy (b) (4)	10 Nov 2020 13:15:35
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 13:15:09
User entered empty.	Lisa Macoy (b) (4)	10 Nov 2020 13:15:09
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'PLACED ON MEDS TO TREAT, due to MI' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:55
User entered 'placed on meds to treat MI'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 13:15:09

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Skin injuries and mechanical dermatoses, PT: Decubitus ulcer, LLT: Bed sore - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 19:47:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 19:47:22
Data point term sent to Coder	System	11 Mar 2021 16:54:36
Coding entries removed.	Lisa Macoy (b) (4)	11 Mar 2021 16:53:45
	(b) (4)	
User entered 'BEDSORE' reason for change: Data Entry Error	Lisa Macoy (b) (4)	11 Mar 2021 16:53:45
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Infected skin ulcer, LLT: Infected skin ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:34:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:34:46
	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 20:28:11
User entered 'infected wound- bedsore'	Lisa Macoy (b) (4)	16 Nov 2020 20:27:16
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '13 Nov 2020'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	11 Mar 2021 16:53:45
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.'	(b) (4), (b) (6)	26 Jan 2021 04:40:05
answered with 'updated' (Site from DM).		
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.'	Lisa Macoy (b) (4)	24 Jan 2021 21:43:07
answered with 'updated' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	24 Jan 2021 21:43:01
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 04:51:19
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	16 Nov 2020 20:27:16
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty; reason for change New Information	Lisa Macoy (b) (4) (b) (4)	11 Mar 2021 16:53:45
User entered '27 Nov 2020' reason for change: New Information	Lisa Macoy (b) (4) (b) (4)	24 Jan 2021 21:43:01
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 14:18:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 14:18:50
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	17 Nov 2020 14:18:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 20:27:16
User entered empty.	Lisa Macoy (b) (4)	16 Nov 2020 20:27:16
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	16 Nov 2020 20:27:16
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Applicable (NOT APPLICABLE)'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:00:32
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	14 Dec 2020 16:38:01
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:07:07
User entered 'I'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Per DM CLR - RQ: Site's response noted. However, please confirm what has been updated as this field is still not ticked. Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:18:40
Query 'Per DM CLR - RQ: Site's response noted. However, please confirm what has been updated as this field is still not ticked. Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	19 Feb 2021 13:02:13
User entered '1' reason for change: New Information	Lisa Macoy (b) (4) (b) (4)	19 Feb 2021 13:02:06
User opened query 'Per DM CLR - RQ: Site's response noted. However, please confirm what has been updated as this field is still not ticked. Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 09:56:17
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 06:09:07
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	24 Jan 2021 21:43:15
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 04:51:28

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	11 Mar 2021 16:53:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	Lisa Macoy (b) (4)	24 Jan 2021 21:43:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	17 Nov 2020 14:20:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Nov 2020 14:20:31
	System	17 Nov 2020 14:20:31
	Lisa Macoy (b) (4)	17 Nov 2020 14:20:31
	(b) (4)	
	System	16 Nov 2020 20:27:16
	Lisa Macoy (b) (4)	16 Nov 2020 20:27:16
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'occurred after her SAE- due to SAE and not due to study product'	Lisa Macoy (b) (4) (b) (4)	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 14:18:50

US3532170

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 20:27:16

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:25:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:25:31
User closed query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:40:40
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	27 Mar 2021 09:19:41
Data point term sent to Coder	System	26 Mar 2021 17:53:29
Query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:53:19
DataPoint Un-verified.	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:53:12
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:53:12
User entered 'SHORTNESS OF BREATH- etiology unknown, suspect mediation induced, not COVID-19. Limited episode.' reason for change: Per Query Resolution	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:53:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User opened query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 15:43:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 21:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 21:04:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

1920 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Feb 2021 21:03:34
User entered 'shortness of breath'	Lisa Macoy (b) (4)	02 Feb 2021 21:02:50
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '1 Dec 2020'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User entered empty.	System	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '1 Dec 2020'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User entered empty.	System	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 21:03:09
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:03:09
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:02:50
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	02 Feb 2021 21:06:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 21:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 21:03:09
User entered 'None (NONE)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	02 Feb 2021 21:03:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 21:02:50
User entered empty.	System	02 Feb 2021 21:02:50
	Lisa Macoy (b) (4)	02 Feb 2021 21:02:50
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Per DM CLR - RQ: Site's response noted. However, since LISINOPRIL was indicated for HYPERTENSION and not for this AE, please un-tick this field as there is no medication directly used to treat this AE.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 04:13:47
Query 'Per DM CLR - RQ: Site's response noted. However, since LISINOPRIL was indicated for HYPERTENSION and not for this AE, please un-tick this field as there is no medication directly used to treat this AE.' answered with 'Per Subject, the PCP changed the dose, as possible side effect, for treatment of this AE even though the drug is not used for this AE specifically ' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:15:35
User opened query 'Per DM CLR - RQ: Site's response noted. However, since LISINOPRIL was indicated for HYPERTENSION and not for this AE, please un-tick this field as there is no medication directly used to treat this AE.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:36:42
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 04:40:21
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Lisinopril dose was changed per cardio to trial if dose was cause of event, but drug is still indicate for hypertension. ' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:36:57

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User entered 'I'	(b) (4), (b) (6) (b) (4) Lisa Macoy (b) (4) (b) (4)	19 Feb 2021 09:56:45 02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 21:03:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:03:09
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:02:50
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
User closed query 'Per DM CLR - RQ: Site's response noted. However, please confirm if the patient underwent any diagnostic procedures using these diagnostic tools. If yes, the diagnostic procedure should be recorded in the ConProc eCRF. Otherwise, confirm that NO diagnostic procedure are performed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:48:35
Query 'Per DM CLR - RQ: Site's response noted. However, please confirm if the patient underwent any diagnostic procedures using these diagnostic tools. If yes, the diagnostic procedure should be recorded in the ConProc eCRF. Otherwise, confirm that NO diagnostic procedure are performed.' answered with 'no procedures done post use of diagnostic tools' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:53:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User opened query 'Per DM CLR - RQ: Site's response noted. However, please confirm if the patient underwent any diagnostic procedures using these diagnostic tools. If yes, the diagnostic procedure should be recorded in the ConProc eCRF. Otherwise, confirm that NO diagnostic procedure are performed.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:35:23
User closed query 'Per DM CLR: Narrative = ECHO AND EVEN MONITOR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 04:48:11
Query 'Per DM CLR: Narrative = ECHO AND EVEN MONITOR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'ECHO and event monitor are diagnostic tools not procedures. Please clarify.' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	19 Feb 2021 13:11:52
User entered 'SEEN BY CARDIOLOGIST, ECHO AND EVENT MONITOR. CHANGE IN LISINOPRIL.' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	19 Feb 2021 13:10:49

PRODUCTION RELEASE (v12.003
EAB) (1725)

1953 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = ECHO AND EVEN MONITOR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 09:56:40
User entered 'seen by cardiologist, echo and even monitor. Change in lisinopril.'	Lisa Macoy (b) (4)	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User entered '0'	System	02 Feb 2021 21:03:09

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58
User entered 'I'	System	02 Feb 2021 21:02:50

US3532170

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:13:58

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 21:06:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 21:06:33
	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 21:05:36
User entered 'syncope'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '14 Jan 2021'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User entered empty.	System	02 Feb 2021 21:04:44

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '14 Jan 2021'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User entered empty.	System	02 Feb 2021 21:04:44

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Grade 3/Severe (Grade 3/Severe)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Applicable (NOT APPLICABLE)'	Lisa Macoy (b) (4)	02 Feb 2021 21:07:16
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'I'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:04:44
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User entered '0'	System	02 Feb 2021 21:04:44

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50
User entered '1'	System	02 Feb 2021 21:04:44

US3532170

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:50

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Intention tremor, LLT: Intention tremor - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:09:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:09:57
Data point term sent to Coder	System	02 Feb 2021 21:09:11
User entered 'benign intention tremors'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '28 Jan 2021'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Applicable (NOT APPLICABLE)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'I'	Lisa Macoy (b) (4)	02 Feb 2021 21:08:31
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Feb 2021 21:08:31

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 18:14:44
User entered		
'USA-US077-2021-mRNA-1273-P301000003'	System	23 Feb 2021 18:08:51
User entered 'New'	(b) (4), (b) (6)	23 Feb 2021 18:08:51

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'PV Query: Please confirm if left buttock wound infection is a continuation of bedsore and determine the start date of event.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 17:42:17
Query 'PV Query: Please confirm if left buttock wound infection is a continuation of bedsore and determine the start date of event.' answered with 'wound is a continuation, infection is new onset' (Site from Safety).	Lisa Macoy (b) (4)	05 Mar 2021 16:20:36
	(b) (4)	
User opened query 'PV Query: Please confirm if left buttock wound infection is a continuation of bedsore and determine the start date of event.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:46:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Wound infection, LLT: Wound infection - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:13:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:13:58
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 17:47:44
User entered 'Wound infection left buttock'	Lisa Macoy (b) (4)	22 Feb 2021 17:46:58
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '17 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 20:33:24
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '9 Mar 2021' reason for change: Data Entry Error	Lisa Macoy (b) (4)	10 Mar 2021 20:33:24
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'still pending under treatment' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 17:42:14
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	Lisa Macoy (b) (4)	05 Mar 2021 16:20:59
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 21:44:44
	Lisa Macoy (b) (4)	22 Feb 2021 17:46:58
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Grade 4 (Grade 4)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	22 Feb 2021 17:47:44
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	22 Feb 2021 17:46:58
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	22 Feb 2021 17:46:58
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	22 Feb 2021 17:46:58
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Per CDM: Please leave this query open until the Hospital Discharge Date is updated. Thank You.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 03:54:11
Query 'Per CDM: Please leave this query open until the Hospital Discharge Date is updated. Thank You.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 18:10:29
User opened query 'Per CDM: Please leave this query open until the Hospital Discharge Date is updated. Thank You.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 11:29:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 05:05:11
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'discharge pending' (Site from System).	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:48:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Feb 2021 17:47:44
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	22 Feb 2021 17:47:44
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Feb 2021 17:47:44
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:47:44

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User entered '0'	System	22 Feb 2021 17:46:58
	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '19 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'PV Query: Please provide hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:13:48
Query 'PV Query: Please provide hospital discharge date when available.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	10 Mar 2021 18:10:36
	(b) (4)	
User entered '24 Feb 2021' reason for change: New Information	Lisa Macoy (b) (4)	10 Mar 2021 18:10:10
	(b) (4)	
User opened query 'PV Query: Please provide hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:45:49
User entered empty.	Lisa Macoy (b) (4)	22 Feb 2021 17:46:58
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'None (NONE)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 18:12:20
User entered 'Not Applicable (NOT APPLICABLE)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	22 Feb 2021 17:46:58
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) (b) (4)	29 Mar 2021 14:52:13
Query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.' answered with 'Tylenol not the conmed for this AE' (Site from Safety). DataPoint Verified.	Evan Anderson (b) (4) (b) (4)	27 Mar 2021 09:19:41
Query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.'	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:54:42
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User opened query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:59:18
User closed query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:13:52
Query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.' answered with 'Tylenol is not the medication. antibiotics listed correlate with this AE' (Site from Safety).	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:49:20
User opened query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:43:07
User entered 'I'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:52:18
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:52:15
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
Query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 17:54:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 17:54:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User opened query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:59:52
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:59:43
User closed query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:14:10

PRODUCTION RELEASE (v12.003
EAB) (1725)

2058 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:14:07
User closed query 'PV Query: When available, please provide blood culture results.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:14:01
Query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	10 Mar 2021 19:57:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' answered with 'done' (Site from Safety).	Lisa Macoy (b) (4)	10 Mar 2021 19:56:48
Query 'PV Query: When available, please provide blood culture results.' answered with 'done' (Site from Safety).	Lisa Macoy (b) (4)	10 Mar 2021 19:56:37
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4)	10 Mar 2021 18:12:20
User opened query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:43:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:42:31
User opened query 'PV Query: When available, please provide blood culture results.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:42:09

PRODUCTION RELEASE (v12.003
EAB) (1725)

2059 of 3412

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:14:24
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	11 Mar 2021 16:55:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
	(b) (4)	10 Mar 2021 20:33:24
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:45:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lisa Macoy (b) (4)	22 Feb 2021 17:46:58
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:52:20
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
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 'updated' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 17:55:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
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)	14 Mar 2021 17:00:10
User closed query 'Per DM CLR: Narrative = ADMITTED TO HOSPITAL 2/19/2020 FOR IV ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 04:06:34
User closed query 'PV Query: Fever of 102.6 reported, please confirm this is degrees Fahrenheit.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:14:36
User closed query 'PV Query: Please provide applicable start/stop dates for Medical History of generalized muscle aches and seasonal allergies.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:14:30
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)	11 Mar 2021 18:14:28
User closed query 'PV Query: As subject only received one dose of mRNA-1273. Please update action taken with study drug (currently Not Applicable)' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:14:26

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: As subject only received one dose of mRNA-1273. Please update action taken with study drug (currently Not Applicable)' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	11 Mar 2021 16:55:46
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 'updated' (Site from Safety).	Lisa Macoy (b) (4)	10 Mar 2021 20:30:21
Query 'PV Query: Please provide applicable start/stop dates for Medical History of generalized muscle aches and seasonal allergies.' answered with 'not related to this AE' (Site from Safety).	Lisa Macoy (b) (4)	10 Mar 2021 20:30:14
Query 'Per DM CLR: Narrative = ADMITTED TO HOSPITAL 2/19/2020 FOR IV ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4)	10 Mar 2021 20:28:14
Query 'PV Query: Fever of 102.6 reported, please confirm this is degrees Fahrenheit.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	10 Mar 2021 20:28:01
User opened query 'Per DM CLR: Narrative = ADMITTED TO HOSPITAL 2/19/2020 FOR IV ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:32:22
User opened query 'PV Query: Fever of 102.6 reported, please confirm this is degrees Fahrenheit.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:46:23
User opened query 'PV Query: Please provide applicable start/stop dates for Medical History of generalized muscle aches and seasonal allergies.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:45:26
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)	03 Mar 2021 21:44:08

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As subject only received one dose of mRNA-1273. Please update action taken with study drug (currently Not Applicable)' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:43:54
User entered 'Bedsore post CABAG 9/2020. Treated for infection Nov 2020. Wound vac drain placed 20JAN due to bedsore not healing. Subject is diabetic. Subjecct with ever chills and worsening bedsore 2/17/20 and admitted to hospital 2/19/2020 for IV antibiotics'	Lisa Macoy (b) (4)	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User entered '0'	System	22 Feb 2021 17:46:58

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 18:14:44
User entered	(b) (4), (b) (6)	23 Feb 2021 18:10:11
'USA-US077-2021-mRNA-1273-P301000003'		

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:51:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:51:01
Data point term sent to Coder	System	22 Feb 2021 17:50:50
User entered 'Sepsis'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '19 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:37:05
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Un-verified.	Lisa Macoy (b) (4)	26 Mar 2021 17:56:30
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	26 Mar 2021 17:56:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:36:55
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Evan Anderson (b) (4)	29 Mar 2021 14:52:26 27 Mar 2021 09:19:41
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Mar 2021 17:57:07 26 Mar 2021 17:57:07
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety). User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	Lisa Macoy (b) (4) System	26 Mar 2021 17:56:38 26 Mar 2021 17:56:30
DataPoint Un-verified.	Lisa Macoy (b) (4)	26 Mar 2021 17:56:30
User entered '24 Feb 2021' reason for change: New Information	Lisa Macoy (b) (4)	26 Mar 2021 17:56:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) Lisa Macoy (b) (4)	14 Mar 2021 16:56:52 22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Grade 4 (Grade 4)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	22 Feb 2021 17:51:15
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	22 Feb 2021 17:50:48
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 05:05:26
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'discharge pending' (Site from System).	Lisa Macoy (b) (4)	22 Feb 2021 17:51:30
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		22 Feb 2021 17:51:15
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	22 Feb 2021 17:51:15
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	22 Feb 2021 17:51:15
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4)	22 Feb 2021 17:51:15
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Feb 2021 17:50:48
User entered '0'	Lisa Macoy (b) (4)	22 Feb 2021 17:50:48
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '19 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) (b) (4)	29 Mar 2021 14:52:29
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'sent 10MAR2021' (Site from Safety). DataPoint Verified.	Evan Anderson (b) (4) (b) (4) Lisa Macoy (b) (4) (b) (4)	27 Mar 2021 09:19:41 26 Mar 2021 17:58:23
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Mar 2021 20:48:00 14 Mar 2021 17:02:14
User closed query 'PV Query: Please provide hospital discharge date when available.' (Site from Safety). Query 'PV Query: Please provide hospital discharge date when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6) (b) (4) Lisa Macoy (b) (4) (b) (4)	11 Mar 2021 18:15:13 10 Mar 2021 20:12:21
User entered '24 Feb 2021' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 20:12:14
User opened query 'PV Query: Please provide hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:55:33
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered 'Not Applicable (NOT APPLICABLE)'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered '0'	Lisa Macoy (b) (4)	22 Feb 2021 17:50:48
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) (b) (4)	29 Mar 2021 14:52:32
Query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.' answered with 'Tylenol is not the conmed for this AE' (Site from Safety). DataPoint Verified.	Evan Anderson (b) (4) (b) (4) Lisa Macoy (b) (4) (b) (4)	27 Mar 2021 09:19:41 26 Mar 2021 17:58:50
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User opened query 'PV Query: Tylenol is listed in subject's concomitant medication indicated for general body aches. Please provide applicable start/stop date.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 04:17:37
User closed query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:55:51
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	11 Mar 2021 18:15:17 11 Mar 2021 17:25:14
Query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 20:12:29

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:32:53
User opened query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:54:04
User entered 'I'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:52:37
User closed query 'PV Query: When available, please provide blood culture results.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:52:35
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
Query 'PV Query: When available, please provide blood culture results.' answered with 'sent 10MAR2021' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 17:59:15
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Sent10MAR2021' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 17:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:55:14
User opened query 'PV Query: When available, please provide blood culture results.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:54:56

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:15:33
User closed query 'PV Query: When available, please provide blood culture results.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:15:30
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	11 Mar 2021 17:25:41
Query 'PV Query: When available, please provide blood culture results.' answered with 'updated' (Site from Safety).	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4)	10 Mar 2021 20:14:18
	(b) (4)	
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 20:14:04
User opened query 'PV Query: When available, please provide blood culture results.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:53:33
User entered '0'	(b) (4)	03 Mar 2021 21:53:16
	(b) (4)	
	Lisa Macoy (b) (4)	22 Feb 2021 17:50:48
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:37:14
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:52:39
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 17:59:24
DataPoint Un-verified.	Lisa Macoy (b) (4)	26 Mar 2021 17:57:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Lisa Macoy (b) (4)	26 Mar 2021 17:57:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:57:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lisa Macoy (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:00
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:37:19
User closed query 'PV Query: Fever of 102.6 reported, please confirm this is degrees Fahrenheit.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:52:46
User closed query 'PV Query: Please provide applicable start/stop dates for Medical History of generalized muscle aches and seasonal allergies.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:52:45
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)	29 Mar 2021 14:52:43
User closed query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 14:52:41
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:19:41
Query 'PV Query: Fever of 102.6 reported, please confirm this is degrees Fahrenheit.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 18:01:40
DataPoint Un-verified.	Lisa Macoy (b) (4)	26 Mar 2021 18:01:34
User entered 'INFECTED BEDSORE. SYMPTOMS OF HYPOTENSION, FEVER 102.6F AND LEUKOCYTOSIS. BLOOD CULTURES PENDING. CURRENTLY ON ROCEPHIN AND VANCOMYCIN' reason for change: Data Entry Error	Lisa Macoy (b) (4)	26 Mar 2021 18:01:34
Query 'PV Query: Please provide applicable start/stop dates for Medical History of generalized muscle aches and seasonal allergies.' answered with 'ongoing' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 18:01:17
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 'sent 10MAR2021' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 18:00:59

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' answered with 'updated' (Site from Safety).	Lisa Macoy (b) (4)	26 Mar 2021 17:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:48:00
User closed query 'Per DM CLR: Narrative = BLOOD CULTURES. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 08:30:52
User closed query 'Per DM CLR: Narrative = CURRENTLY ON ROCEPHIN AND VANCOMYCIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 04:18:55
User opened query 'PV Query: Fever of 102.6 reported, please confirm this is degrees Fahrenheit.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:57:59
User opened query 'PV Query: Please provide applicable start/stop dates for Medical History of generalized muscle aches and seasonal allergies.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:57:26
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)	14 Mar 2021 16:56:28
User opened query 'PV Query: Please provide updated treatment regimen and any additional procedures performed for event as applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:56:10
Query 'Per DM CLR: Narrative = CURRENTLY ON ROCEPHIN AND VANCOMYCIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4)	11 Mar 2021 17:25:57

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = BLOOD CULTURES. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	11 Mar 2021 17:25:51
User opened query 'Per DM CLR: Narrative = CURRENTLY ON ROCEPHIN AND VANCOMYCIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	09 Mar 2021 03:32:45
User opened query 'Per DM CLR: Narrative = BLOOD CULTURES. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	09 Mar 2021 03:32:40
User entered 'infected bedsore. Symptoms of hypotension, fever 102.6 and leukocytosis. Blood cultures pending. Currently on Rocephin and Vancomycin'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User entered '0'	System	22 Feb 2021 17:50:48

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of legs - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Mar 2021 13:45:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:45:27
Data point term sent to Coder	System	30 Mar 2021 13:00:24
User entered 'bilateral leg swelling'	Lisa Macoy (b) (4) (b) (4)	30 Mar 2021 13:00:05

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '14 Jan 2021'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:00:05

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 02:16:45
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'still ongoing' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	06 Apr 2021 15:50:07
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 09:41:09
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	30 Mar 2021 13:00:05

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:00:05

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	09 Apr 2021 08:26:24
User entered empty.	Lisa Macoy (b) (4) (b) (4)	30 Mar 2021 13:00:05

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

None

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 15:50:29
User entered '0'	System	30 Mar 2021 13:00:05
	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4)	06 Apr 2021 15:50:29
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Mar 2021 13:00:05
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
User entered 'Subject with history of hypertension, MI, post CABG, Type II diabetes'	(b) (4) Lisa Macoy (b) (4) (b) (4)	30 Mar 2021 13:00:05

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 13:00:05

US3532170

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 13:00:05

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Wheezing - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 20:35:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 20:35:12
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 20:34:16
User entered 'wheezing'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered '14 Sep 2020'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User entered empty.	System	16 Apr 2021 20:33:55

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered '18 Sep 2020'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User entered empty.	System	16 Apr 2021 20:33:55

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	19 Apr 2021 11:11:59
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	16 Apr 2021 20:36:49
User entered 'No (N)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 05:30:23
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Wheezing secondary to primary diagnosis' (Site from System).	Lisa Macoy (b) (4)	16 Apr 2021 20:36:45
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	16 Apr 2021 20:33:55
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Lisa Macoy (b) (4)	19 Apr 2021 11:11:11
	(b) (4)	
User entered '07 Sep 2020'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Lisa Macoy (b) (4)	19 Apr 2021 11:11:11
	(b) (4)	
User entered '06 Oct 2020'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	19 Apr 2021 11:11:11
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Lisa Macoy (b) (4)	19 Apr 2021 11:11:11
	(b) (4)	
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 06:03:43
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered with 'not in ICU for this AE but AE 1' (Site from System).	Lisa Macoy (b) (4)	16 Apr 2021 20:38:24
	(b) (4)	
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	16 Apr 2021 20:33:55
User entered '9'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	19 Apr 2021 11:11:59
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Apr 2021 20:36:49
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'None (NONE)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'I'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User entered 'AE occurred during hospitalization 07SEP2020 until 06OCT2020 and WAS NOT RELATED TO HOSPITALIZATION OR PROLONGED HOSPITALIZATION BUT WAS SECONDARY TO PRIMARY DIAGNOSIS Acute Myocardial infarction' reason for change: New Information	Lisa Macoy (b) (4)	19 Apr 2021 11:11:11
	(b) (4)	
User entered 'AE was not related to hospitalization or prolonged hospitalization but was secondary to primary diagnosis' reason for change: New Information	Lisa Macoy (b) (4)	16 Apr 2021 20:44:18
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	16 Apr 2021 20:33:55
	(b) (4)	

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User entered '0'	System	16 Apr 2021 20:33:55

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User entered '1'	System	16 Apr 2021 20:33:55

US3532170

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:47:56
User entered '0'	System	19 Apr 2021 11:11:11
User entered '1'	System	16 Apr 2021 20:33:55

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 06:37:15
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 13:05:50
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 09:35:50
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:14:41

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Aug 2020 17:17:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:17:45
Data point term sent to Coder	System	28 Aug 2020 17:16:25
User entered 'metformin'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:15:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'type II diabetes'	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '1000'	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'twice daily (BID)'	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 08:52:55
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	16 Oct 2020 13:38:13
User entered 'UN UNK 2016' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	16 Oct 2020 13:38:07
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 15:58:25
User entered 'un UNK 2015'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:15:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:15:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 17:15:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:15:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:15:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Apr 2021 21:11:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 21:11:51
Data point term sent to Coder	System	16 Apr 2021 21:10:59
Coding entries removed.	Lisa Macoy (b) (4)	16 Apr 2021 21:10:47
Signature has been broken.	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:10:47
User entered 'Levothyroxine' reason for change: Per Query Resolution	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:10:47
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Aug 2020 17:17:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:17:44
Data point term sent to Coder	System	28 Aug 2020 17:16:27
User entered 'synthroid'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'hypothyroidism'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '112' reason for change: New Information	Lisa Macoy (b) (4)	19 Oct 2020 19:43:12
	(b) (4)	
User entered '125'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'ug (ug)'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'un UNK 1985'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:16:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:16:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:16:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:16:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Aug 2020 17:20:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:20:50
Data point term sent to Coder	System	28 Aug 2020 17:19:32
User entered 'Lisinopril'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'hypertension'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '20'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'un UNK 2015'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 13:47:58
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '30 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 13:47:58
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User entered '1'	System	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User entered '1'	System	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:39
User entered '804 (804)'	System	28 Aug 2020 17:18:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:32
User closed query 'please also add Insulin lispo (see discharge summage, p.23)' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:20:30
Query 'please also add Insulin lispo (see discharge summage, p.23)' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	16 Apr 2021 13:36:20
User opened query 'please also add Insulin lispo (see discharge summage, p.23)' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:58:36
Query 'please also add Insulin Glargine and Insulin lispo (see discharge summage, p.23)' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:58:21
User opened query 'please also add Insulin Glargine and Insulin lispo (see discharge summage, p.23)' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:28:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Oct 2020 13:40:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Oct 2020 13:40:29
Data point term sent to Coder	System	16 Oct 2020 13:39:45
Coding entries removed.	Lisa Macoy (b) (4)	16 Oct 2020 13:38:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Aug 2020 07:54:36

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'lantus insulin'	Coder Import (b) (4) (b) (4) System Lisa Macoy (b) (4) (b) (4)	29 Aug 2020 07:54:36 28 Aug 2020 17:20:34 28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:38:46
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:38:39
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'type II diabetes'	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '18'	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 21:12:07
User entered 'Other (OTHER)' reason for change:	Lisa Macoy (b) (4)	16 Apr 2021 21:12:07
Data Entry Error	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'IU (IU)'	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 21:12:07
User entered 'units' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Apr 2021 21:12:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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) (4), (b) (6)	19 Oct 2020 08:50:36
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	16 Oct 2020 13:38:56
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	16 Oct 2020 13:38:49
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)	08 Oct 2020 15:58:01
Query "'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.'	(b) (4), (b) (6)	08 Oct 2020 15:57:48
"		
' canceled (Site from DM).		
User opened query "'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.'	(b) (4), (b) (6)	08 Oct 2020 15:57:46
"		
' (Site from DM).		
User entered 'Intramuscular (INTRAMUSCULAR)'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '16 Feb 2020'	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 13:49:12
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	30 Oct 2020 13:49:12
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User entered '1'	System	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User entered '1'	System	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:14:46
User entered '804 (804)'	System	28 Aug 2020 17:19:53

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:21:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:21:39
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 17:20:35
User entered 'multi-vitamin'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 13:31:48
Query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Dec 2020 18:48:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Dec 2020 18:48:07
User opened query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:54:41
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:20:35

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'general health'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'I'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'tablet (TABLET)'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'un UNK 1985'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 13:49:51
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'un Sep 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	30 Oct 2020 13:49:51
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:20:35
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User entered '1'	System	28 Aug 2020 17:20:35

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User entered '1'	System	28 Aug 2020 17:20:35

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:39:45
User entered '804 (804)'	System	28 Aug 2020 17:20:35

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:15:56
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 Apr 2021 21:15:56
Data point term sent to Coder	System	16 Apr 2021 21:15:01
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 21:14:31
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 23:17:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 23:17:46
Data point term sent to Coder	System	28 Aug 2020 17:21:36
User entered 'vitamin D'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:21:14

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 21:14:31
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	16 Apr 2021 21:14:31
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 21:14:31
	(b) (4)	
User entered 'General Health' reason for change:	Lisa Macoy (b) (4)	16 Apr 2021 21:14:31
Data Entry Error	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'low vitamin D levels'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '1'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'tablet (TABLET)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:21:14

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '18 Feb 2020'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:14
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:21:14

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:21:14

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:21:14

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Nov 2020 13:53:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 13:53:40
Data point term sent to Coder Coding entries removed.	System Lisa Macoy (b) (4)	09 Nov 2020 13:53:38 09 Nov 2020 13:52:53
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)	28 Aug 2020 17:23:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:23:44
Data point term sent to Coder User entered 'Tylenol'	System Lisa Macoy (b) (4)	28 Aug 2020 17:22:37 28 Aug 2020 17:21:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:11:20
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Subject stated takes Tylenol just to "feel better" no specific reason. ' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 11:51:12
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:39:33
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	28 Aug 2020 17:21:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'generalized muscle aches' reason for change: Data Entry Error	Lisa Macoy (b) (4)	09 Nov 2020 13:52:53
	(b) (4)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 06:31:58
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'general health per patient interview' (Site from DM).	Lisa Macoy (b) (4)	19 Oct 2020 19:44:22
	(b) (4)	
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:50:24
User entered 'general health'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
	(b) (4)	
User closed query 'please check with source if should be 650 mg' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 02:11:18
Query 'please check with source if should be 650 mg' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	16 Apr 2021 20:15:07
	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 20:14:49
	(b) (4)	
User entered '650' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Apr 2021 20:14:49
	(b) (4)	
User opened query 'please check with source if should be 650 mg' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:56:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 650 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 06:30:58
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 650 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4)	19 Oct 2020 19:45:24
	(b) (4)	
User entered '325' reason for change: Data Entry Error	Lisa Macoy (b) (4)	19 Oct 2020 19:45:14
	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 650 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:50:18
User entered '1'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	19 Oct 2020 19:45:14
	(b) (4)	
User entered 'tablet (TABLET)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'as needed (PRN)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'I'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	28 Aug 2020 17:21:46
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:21:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:21:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:21:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 07:38:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 07:38:36
Data point term sent to Coder	System	20 Oct 2020 17:40:06
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:39:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:32:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:32:28
Data point term sent to Coder	System	19 Oct 2020 19:48:31
User entered 'acetaminophen-hydrocodone'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION- post CABG treatment protocol' reason for change: Data Entry Error	(b) (4)	
	Lisa Macoy (b) (4)	20 Oct 2020 17:39:40
	(b) (4)	
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 19:47:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 325/5).' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 10:35:07
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 325/5).' answered with 'updated' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	07 Nov 2020 21:04:08
User entered '325 / 5' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	07 Nov 2020 21:04:02
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 325/5).' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:40:56
User entered '5'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'as needed (PRN)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12 Sep 2020' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 13:51:48
User entered '6 Oct 2020'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:47:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 13:50:28
User entered 'Yes (Y)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:47:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	30 Oct 2020 13:51:48
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	30 Oct 2020 13:50:28
User entered '19 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 13:50:28
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:47:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:14:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
User entered empty.	System	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
User entered empty.	System	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:25
User entered empty.	System	19 Oct 2020 19:47:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 09:04:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 09:04:34
Data point term sent to Coder	System	20 Oct 2020 17:40:06
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:40:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:49:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:49:43
Data point term sent to Coder	System	19 Oct 2020 19:48:33
User entered 'amiodarone'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	(b) (4)	
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	20 Oct 2020 17:40:02
	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:48:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '200'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:48:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:48:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:48:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12 Sep 2020' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 13:57:29
User entered '6 Oct 2020'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:48:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	19 Jan 2021 14:27:45
User entered 'Yes (Y)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:48:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	19 Jan 2021 14:27:45
	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:48:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:19:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:48:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
User entered '1'	System	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
User entered '1'	System	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:15
User entered '804 (804)'	System	19 Oct 2020 19:48:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 11:53:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 11:53:30
Data point term sent to Coder Coding entries removed.	System	09 Nov 2020 11:52:45
	Lisa Macoy (b) (4)	09 Nov 2020 11:52:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:15:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:15:39
Data point term sent to Coder Coding entries removed.	System	20 Oct 2020 17:41:10
	Lisa Macoy (b) (4)	20 Oct 2020 17:40:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 04:52:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'vitamin C'	Coder Import (b) (4) (b) (4) System Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 04:52:40 19 Oct 2020 19:49:35 19 Oct 2020 19:49:06

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	09 Nov 2020 11:52:22
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:14:02
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 11:52:32
User entered 'General Health' reason for change: Per Query Resolution	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 11:52:22
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:41:25
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:40:13
User entered 'myocardial infarction'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:49:06

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '500'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '13 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 13:58:04
	(b) (4)	
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	02 Feb 2021 21:14:05
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'un Nov 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	02 Feb 2021 21:14:05
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:06
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User entered '1'	System	19 Oct 2020 19:49:06

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User entered '1'	System	19 Oct 2020 19:49:06

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:02
User entered '804 (804)'	System	19 Oct 2020 19:49:06

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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)	21 Oct 2020 09:33:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 09:33:33
Data point term sent to Coder Coding entries removed.	System	20 Oct 2020 17:41:10
	Lisa Macoy (b) (4)	20 Oct 2020 17:40:24
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)	19 Oct 2020 19:51:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 19:51:27
Data point term sent to Coder User entered 'Aspirin'	System	19 Oct 2020 19:50:37
	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4)	20 Oct 2020 17:40:24
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '81'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '13 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 13:59:28
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:20:09
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 19:49:47

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 09:42:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 09:42:26
Data point term sent to Coder	System	20 Oct 2020 17:41:10
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:40:35
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)	19 Oct 2020 19:51:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:51:28
Data point term sent to Coder	System	19 Oct 2020 19:50:39
User entered 'atorvastatin'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	(b) (4)	
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	20 Oct 2020 17:40:35
	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:50:38
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '80'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:50:38
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:50:38
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:50:38
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 13:59:47
User entered '6 Oct 2020'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:50:38
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	02 Feb 2021 21:14:32
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '28 Jan 2021' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 21:14:32
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:50:38
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:21:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
User entered '1'	System	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
User entered '1'	System	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:33
User entered '804 (804)'	System	19 Oct 2020 19:50:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: MYROXYLON BALSAMUM VAR. PEREIRAE;RICINUS COMMUNIS OIL, PRODUCTSYNONYM: VENELEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Oct 2020 09:47:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 09:47:35
Data point term sent to Coder	System	20 Oct 2020 17:41:10
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:40:46
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: MYROXYLON BALSAMUM VAR. PEREIRAE;RICINUS COMMUNIS OIL, PRODUCTSYNONYM: VENELEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:53:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:53:26
Data point term sent to Coder	System	19 Oct 2020 19:51:50
User entered 'Venelex'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	(b) (4)	
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	20 Oct 2020 17:40:46
	(b) (4)	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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) (4), (b) (6)	10 Nov 2020 05:11:48
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 'there is no percentage for this drug' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 11:57:19
User entered '1' reason for change: Per Query Resolution	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 11:57:05
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 Nov 2020 14:42:26
User entered '788'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Per Query Resolution	Lisa Macoy (b) (4)	09 Nov 2020 11:57:05
User entered 'mg (mg)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:51:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'application' reason for change: Per	(b) (4)	
Query Resolution	Lisa Macoy (b) (4)	09 Nov 2020 11:57:05
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:51:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'twice daily (BID)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:51:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Topical (TOPICAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:51:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '14 Sep 2020' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:02:04
User entered '6 Oct 2020'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:51:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:02:04
User entered 'Yes (Y)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:51:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 14:02:04
	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:51:26
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
User entered '2'	System	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
User entered '1'	System	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:42
User entered '804 (804)'	System	19 Oct 2020 19:51:26

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 12:04:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 12:04:40
Data point term sent to Coder Coding entries removed.	System	20 Oct 2020 17:41:10
	Lisa Macoy (b) (4)	20 Oct 2020 17:40:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Oct 2020 04:33:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Oct 2020 04:33:32
Data point term sent to Coder	System	19 Oct 2020 19:52:51
User entered 'colace'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4)	20 Oct 2020 17:40:59
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '100'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'twice daily (BID)'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '14 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 14:02:33
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 19:52:08

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 12:51:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 12:51:31
Data point term sent to Coder	System	20 Oct 2020 17:41:11
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:41:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:36:29
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 Oct 2020 04:36:29
Data point term sent to Coder	System	19 Oct 2020 19:53:55
User entered 'doxycycline'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 10:40:28
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'this drug was prevention of infection of surgical sites from CABG procedure and part of the protocol' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 11:58:33
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:42:54
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:41:10
User entered 'myocardial infarction'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '100'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'twice daily (BID)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '6 Oct 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '8 Oct 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
User entered '2'	System	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
User entered '1'	System	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:45
User entered '804 (804)'	System	19 Oct 2020 19:53:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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.	(b) (4) Coder Import (b) (4) (b) (4)	23 Oct 2020 11:40:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 11:40:38
Data point term sent to Coder	System	20 Oct 2020 17:42:11
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:41:23
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)	20 Oct 2020 04:40:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:40:40
Data point term sent to Coder	System	19 Oct 2020 19:53:56
User entered 'ferrous sulfate'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4)	20 Oct 2020 17:41:23
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '325'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:45
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:45
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:45
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12 Sep 2020' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:03:24
User entered '6 Oct 2020'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:45
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:03:24
User entered 'Yes (Y)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:45
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 14:03:24
	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:53:45
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:22:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
User entered '1'	System	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
User entered '1'	System	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:51
User entered '804 (804)'	System	19 Oct 2020 19:53:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Oct 2020 19:20:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:20:30
Data point term sent to Coder	System	20 Oct 2020 17:42:11
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:41:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:20:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:20:31
Data point term sent to Coder	System	19 Oct 2020 19:54:58
User entered 'lasix'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4)	20 Oct 2020 17:41:34
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '40'	Lisa Macoy (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'as needed (PRN)' reason for change:	(b) (4)	
New Information	Lisa Macoy (b) (4)	19 Jan 2021 14:30:44
User entered 'once daily (QD)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:54:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '14 Sep 2020' reason for change: New Information	(b) (4) Lisa Macoy (b) (4)	30 Oct 2020 14:03:56
User entered '6 Oct 2020'	(b) (4) Lisa Macoy (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	(b) (4) Lisa Macoy (b) (4)	02 Feb 2021 21:15:38
User entered 'Yes (Y)'	(b) (4) Lisa Macoy (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 21:15:38
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:54:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:30:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
User entered empty.	System	19 Jan 2021 14:30:44
User entered '1'	System	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
User entered empty.	System	19 Jan 2021 14:30:44
User entered '1'	System	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:57
User entered empty.	System	19 Jan 2021 14:30:44
User entered '804 (804)'	System	19 Oct 2020 19:54:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 13:50:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 13:50:42
Data point term sent to Coder	System	20 Oct 2020 17:42:14
Coding entries removed.	Lisa Macoy (b) (4)	20 Oct 2020 17:41:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 04:43:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 04:43:29
Data point term sent to Coder	System	19 Oct 2020 19:56:00
User entered 'gabapentin'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4)	20 Oct 2020 17:41:45
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '100'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'twice daily (BID)'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:32
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 19:55:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 14:06:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:06:31
Data point term sent to Coder	System	20 Oct 2020 17:42:12
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:41:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:45:32
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 Oct 2020 04:45:32
Data point term sent to Coder	System	19 Oct 2020 19:57:01
User entered 'guaifenesin'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:12:59
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'This drug is part of the protocol for CABG due to subject being supine for so long during recovery ' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 11:59:34
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:43:14
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:41:56
User entered 'myocardial infarction'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '600'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'twice daily (BID)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'un Sep 2020' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:04:35
User entered '6 Oct 2020'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:04:35
User entered 'Yes (Y)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '29 Sep 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 14:04:35
	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
User entered '2'	System	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
User entered '1'	System	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:08
User entered '804 (804)'	System	19 Oct 2020 19:56:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Oct 2020 07:56:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:56:24
Data point term sent to Coder	System	20 Oct 2020 17:43:15
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:42:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:17:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:17:38
Data point term sent to Coder	System	19 Oct 2020 19:57:03
User entered 'magnesium oxide'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	(b) (4)	
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	20 Oct 2020 17:42:14
	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '400'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'twice daily (BID)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '6 Oct 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	02 Feb 2021 21:16:18
User entered 'Yes (Y)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:56:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 21:16:18
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:56:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:26:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
User entered '2'	System	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
User entered '1'	System	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:58
User entered '804 (804)'	System	19 Oct 2020 19:56:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 11:18:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 11:18:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:45
Data point term sent to Coder	System	16 Apr 2021 21:53:42
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 21:52:43
Coding entries removed.	Lisa Macoy (b) (4)	16 Apr 2021 21:52:43
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 21:52:43
User entered 'Metoprolol tartrate' reason for change: New Information	Lisa Macoy (b) (4)	16 Apr 2021 21:52:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL XL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 10:23:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 10:23:34
Data point term sent to Coder	System	20 Oct 2020 17:43:15
Coding entries removed.	Lisa Macoy (b) (4)	20 Oct 2020 17:42:27

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL XL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:55:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:55:28
Data point term sent to Coder	System	19 Oct 2020 19:58:04
User entered 'Toprol-XL'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4)	20 Oct 2020 17:42:27
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 00:34:45
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 21:07:31
Signature has been broken.	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:07:31
User entered '25' reason for change: Data Entry Error	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:07:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User closed query 'please check with source if should be 25 mg' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:24:32
Query 'please check with source if should be 25 mg' answered with 'changed by PCP 01Jan2021' (Site from CRA).	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:37:14
User opened query 'please check with source if should be 25 mg' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:42:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '50' reason for change: New Information	(b) (4) Lisa Macoy (b) (4)	19 Jan 2021 14:31:52
User entered '25'	(b) (4) Lisa Macoy (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:57:33
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:57:33
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12 Sep 2020' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:05:00
User entered '6 Oct 2020'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:57:33
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 00:34:45
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 21:07:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:07:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	(b) (4) Lisa Macoy (b) (4)	19 Oct 2020 19:57:33
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 00:34:45
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	16 Apr 2021 21:52:43
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 21:52:43
Signature has been broken.	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:52:43
User entered '14 Jan 2021' reason for change: New Information	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:52:43
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	16 Apr 2021 21:07:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
User entered '1'	System	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
User entered '1'	System	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:19:48
User entered '804 (804)'	System	19 Oct 2020 19:57:33

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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)	09 Nov 2020 13:57:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 13:57:31
Data point term sent to Coder Coding entries removed.	System Lisa Macoy (b) (4)	09 Nov 2020 13:56:40 09 Nov 2020 13:55:41
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)	25 Oct 2020 06:57:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 06:57:22
Data point term sent to Coder Coding entries removed.	System Lisa Macoy (b) (4)	20 Oct 2020 17:43:15 20 Oct 2020 17:42:37
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)	20 Oct 2020 05:08:32

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Oct 2020 05:08:32
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	19 Oct 2020 19:59:06
User entered 'pantoprazole'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GERD worsened. If yes, please review if an AE of worsening GERD should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 05:19:35
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GERD worsened. If yes, please review if an AE of worsening GERD should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'not worse. Never treated, treatment started per outside of study MD request' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Dec 2020 18:56:48
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GERD worsened. If yes, please review if an AE of worsening GERD should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:57:14
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:14:28
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 13:57:31
User entered 'GERD' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 13:55:41

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:43:36
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4)	20 Oct 2020 17:42:37
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '40'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '12 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 14:05:21
	(b) (4)	
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	02 Feb 2021 21:17:03
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'un Nov 2020' reason for change: New Information	Lisa Macoy (b) (4)	02 Feb 2021 21:17:03
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:58:13
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User entered '1'	System	19 Oct 2020 19:58:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User entered '1'	System	19 Oct 2020 19:58:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:40:22
User entered '804 (804)'	System	19 Oct 2020 19:58:13

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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) Coder Import (b) (4) (b) (4)	25 Oct 2020 04:59:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:59:36
Data point term sent to Coder	System	20 Oct 2020 17:43:17
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:42:47
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) (b) (4)	20 Oct 2020 05:06:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:06:30
Data point term sent to Coder	System	19 Oct 2020 19:59:07
User entered 'potassium chloride'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	(b) (4)	
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	20 Oct 2020 17:42:47
	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:59:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '20'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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) (4), (b) (6)	10 Nov 2020 05:13:52
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:48:03
User entered 'Other (OTHER)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:47:47
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)	03 Nov 2020 14:44:09
User entered 'mg (mg)'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Meq' reason for change: Data Entry Error	(b) (4)	
	Lisa Macoy (b) (4)	09 Nov 2020 14:47:47
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:59:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:59:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:59:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '14 Sep 2020' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:05:59
User entered '6 Oct 2020'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:59:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:05:59
User entered 'Yes (Y)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:59:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '28 Oct 2020' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:05:59
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 19:59:00
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:34:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
User entered '1'	System	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
User entered '1'	System	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:20:20
User entered '804 (804)'	System	19 Oct 2020 19:59:00

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 08:41:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 08:41:40
Data point term sent to Coder	System	09 Nov 2020 13:59:42
Coding entries removed.	Lisa Macoy (b) (4)	09 Nov 2020 13:59:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:30:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:30:41
Data point term sent to Coder	System	20 Oct 2020 17:43:16
Coding entries removed.	Lisa Macoy (b) (4)	20 Oct 2020 17:43:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 04:59:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 04:59:33
Data point term sent to Coder	System	19 Oct 2020 20:00:10
User entered 'sertraline'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:14:13
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 13:59:36
User entered 'ANXIETY post CABG' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 13:59:28
User entered 'Anxiety' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 13:59:16
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:44:37
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:43:01
User entered 'myocardial infarction'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '50'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	02 Feb 2021 21:17:34
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 21:17:34
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User entered '1'	System	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User entered '1'	System	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:24
User entered '804 (804)'	System	19 Oct 2020 19:59:51

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 14:37:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 14:37:33
Data point term sent to Coder Coding entries removed.	System	09 Nov 2020 14:21:04
	Lisa Macoy (b) (4)	09 Nov 2020 14:20:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 09:53:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 09:53:37
Data point term sent to Coder Coding entries removed.	System	20 Oct 2020 17:43:15
	Lisa Macoy (b) (4)	20 Oct 2020 17:43:12

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:49:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:49:37
Data point term sent to Coder	System	19 Oct 2020 20:01:15
User entered 'zofran'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:14:19
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:20:20
User entered 'Nausea' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 14:20:13
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:44:56
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:43:12
User entered 'myocardial infarction'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '4'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'as needed (PRN)'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 14:07:28
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '9 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User entered empty.	System	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User entered empty.	System	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:34
User entered empty.	System	19 Oct 2020 20:00:46

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:47
Data point term sent to Coder	System	16 Apr 2021 13:40:12
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:39:50
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 10:20:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 10:20:28
Data point term sent to Coder	System	20 Oct 2020 17:44:19
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:43:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:30:32
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 Oct 2020 04:30:32

PRODUCTION RELEASE (v12.003
EAB) (1725)

2636 of 3412

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Oct 2020 20:02:16
User entered 'bisacodyl'	Lisa Macoy (b) (4)	19 Oct 2020 20:01:25
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 20:01:25
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4)	20 Oct 2020 17:43:22
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '10'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'as needed (PRN)'	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 20:01:25
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User closed query 'please check with source if should be per rectum' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:58:03
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
Query 'please check with source if should be per rectum' answered with 'updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 13:39:56
	(b) (4)	
User entered 'Rectal (RECTAL)' reason for change:	Lisa Macoy (b) (4)	16 Apr 2021 13:39:50
Data Entry Error	(b) (4)	
User opened query 'please check with source if should be per rectum' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 20:04:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 20:01:25
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	19 Oct 2020 20:01:25
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '16 Sep 2020' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	30 Oct 2020 14:07:46
	(b) (4)	
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 20:01:25
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 02:11:49
User closed query 'please check if should be 12Oct20 per source' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 02:11:39
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 21:24:56
Signature has been broken.	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:24:56
User entered 'No (N)' reason for change: New Information	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:24:56
Query 'please check if should be 12Oct20 per source' answered with 'sept date is correct' (Site from CRA).	Cindy Lubbers (b) (4)	16 Apr 2021 20:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 20:00:13
User opened query 'please check if should be 12Oct20 per source' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:59:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	(b) (4) Lisa Macoy (b) (4)	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 02:11:51
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 21:24:56
Signature has been broken.	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:24:56
User entered '12 Oct 2020' reason for change: New Information	(b) (4) Lisa Macoy (b) (4)	16 Apr 2021 21:24:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4)	19 Oct 2020 20:01:25
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 00:38:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
User entered empty.	System	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
User entered empty.	System	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:04
User entered empty.	System	19 Oct 2020 20:01:25

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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) Coder Import (b) (4)	01 Nov 2020 04:59:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 04:59:43
Data point term sent to Coder	System	20 Oct 2020 17:44:18
Coding entries removed.	Lisa Macoy (b) (4)	20 Oct 2020 17:43:32
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) Coder Import (b) (4)	20 Oct 2020 05:07:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:07:31
Data point term sent to Coder	System	19 Oct 2020 20:02:17
User entered 'polyethylene glycol'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTION POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	Lisa Macoy (b) (4)	20 Oct 2020 17:43:32
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '17'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'g (g)'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '15 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 14:08:02
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:39:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 20:02:10

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA [SENNOSIDE A+B] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 15:33:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 15:33:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:32:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:32:42
Data point term sent to Coder	System	20 Oct 2020 17:44:17
Data point term sent to Coder	System	19 Oct 2020 20:03:19
User entered 'Senna'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'MYOCARDIAL INFARCTIN POST CABG TREATMENT PROTOCOL' reason for change: Data Entry Error	(b) (4) Lisa Macoy (b) (4) (b) (4)	20 Oct 2020 17:43:42
User entered 'myocardial infarctin'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'please check if it should be 17.2 mg (as equal to 2 tabs)' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:27
	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
Query 'please check if it should be 17.2 mg (as equal to 2 tabs)' answered with 'updated' (Site from CRA). Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 13:40:43
	Lisa Macoy (b) (4)	16 Apr 2021 13:40:37
User entered '17.2' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Apr 2021 13:40:37
User opened query 'please check if it should be 17.2 mg (as equal to 2 tabs)' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	14 Apr 2021 19:30:07
	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '8.6'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 00:39:48
DataPoint Un-verified.	Cindy Lubbers (b) (4)	16 Apr 2021 20:32:49
	(b) (4)	
Signature has been broken.	Cindy Lubbers (b) (4)	16 Apr 2021 20:32:49
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Cindy Lubbers (b) (4)	16 Apr 2021 20:32:49
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'please check with source if should be "as needed"' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 02:12:31
Query 'please check with source if should be "as needed"' answered with 'corrected' (Site from CRA).	Cindy Lubbers (b) (4)	16 Apr 2021 20:33:08
User opened query 'please check with source if should be "as needed"' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:49
	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '12 Sep 2020' reason for change: New Information	Lisa Macoy (b) (4)	30 Oct 2020 14:08:24
User entered '6 Oct 2020'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:32:49
User entered '1'	System	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:32:49
User entered '1'	System	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:32:49
User entered '804 (804)'	System	19 Oct 2020 20:03:18

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 14:10:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 14:10:57
Data point term sent to Coder	System	30 Oct 2020 14:09:48
User entered 'Jardiance'	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 14:09:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of TYPE II DIABETES worsened. If yes, please review if an AE of worsening TYPE II DIABETES should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 05:20:09
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of TYPE II DIABETES worsened. If yes, please review if an AE of worsening TYPE II DIABETES should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'no worsening DM, just trial new medication' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Dec 2020 18:49:32
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of TYPE II DIABETES worsened. If yes, please review if an AE of worsening TYPE II DIABETES should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:56:20
User entered 'Type II Diabetes'	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 14:09:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '25'	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 14:09:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 14:09:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '12 Oct 2020'	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	30 Oct 2020 14:09:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 14:09:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 14:09:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 14:09:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Oct 2020 14:12:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 14:12:12
Data point term sent to Coder	System	30 Oct 2020 14:10:51
User entered 'phenergan'	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 14:10:27

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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) (4), (b) (6)	11 Dec 2020 13:24:25
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 'AE has already been reported' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	09 Dec 2020 18:54:50
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:59:09
User entered 'nausea'	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 14:10:27

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '25'	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'as needed (PRN)'	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 14:10:27

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '20 Oct 2020'	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	30 Oct 2020 14:10:27
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 14:10:27

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 14:10:27

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 14:10:27

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 14:30:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 14:30:32
Data point term sent to Coder	System	09 Nov 2020 14:13:59
User entered 'influenza vaccine'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'influenza'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0.5'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mL (mL)'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once (ONCE)'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Intramuscular (INTRAMUSCULAR)'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '04 Oct 2020'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '04 Oct 2020'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User entered empty.	System	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User entered empty.	System	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:21:21
User entered empty.	System	09 Nov 2020 14:13:37

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMPICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Dec 2020 15:52:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:52:52
Data point term sent to Coder	System	14 Dec 2020 16:41:54
User entered 'Ampicillin'	Lisa Macoy (b) (4) (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'INFECTED WOUND- BEDSORE'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'unk'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Other (OTHER)'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'unk'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'four times daily (QID)'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '13 Nov 2020'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	22 Dec 2020 18:03:04
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '27 Nov 2020' reason for change: New Information	(b) (4)	22 Dec 2020 18:03:04
User entered empty.	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User entered '4'	System	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User entered '1'	System	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:49
User entered '804 (804)'	System	14 Dec 2020 16:41:24

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Feb 2021 21:23:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 21:23:33
Data point term sent to Coder	System	02 Feb 2021 21:22:22
User entered 'Lisinopril'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:21:28

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'hypertension'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '2.5'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '10 Dec 2020'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:21:28
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 21:21:28

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 21:21:28

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Feb 2021 21:21:28

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Feb 2021 21:24:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 21:24:32
Data point term sent to Coder	System	02 Feb 2021 21:23:23
User entered 'crestor'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:22:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'hyperlipidemia'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '40'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:22:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '28 Jan 2021'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:22:30
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 21:22:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 21:22:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Feb 2021 21:22:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Feb 2021 12:02:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 12:02:43
Data point term sent to Coder	System	02 Feb 2021 21:24:24
User entered 'Wellbutrin'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:23:34

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'anxiety post CABAG'	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '300'	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:23:34

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '14 Jan 2021'	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4) (b) (4)	02 Feb 2021 21:23:34

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	02 Feb 2021 21:23:34
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 21:23:34

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 21:23:34

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Feb 2021 21:23:34

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Feb 2021 13:08:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 13:08:46
Data point term sent to Coder	System	09 Feb 2021 13:08:21
User entered 'Tylenol'	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 04:21:01
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'solicited event post vaccine dose and did not meet AE criteria' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:34:38

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[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. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:32:27
User entered 'Headache'	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '325'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'as needed (PRN)'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '28 Aug 2020'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '28 Aug 2020'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User entered empty.	System	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User entered empty.	System	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:52
User entered empty.	System	09 Feb 2021 13:07:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Mar 2021 05:44:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 05:44:56
Data point term sent to Coder	System	26 Mar 2021 16:43:59
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 16:43:49
User entered 'AMoxicillin/clavulanate' reason for change: Per Query Resolution	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 16:43:49
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) (b) (4)	08 Mar 2021 04:56:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 04:56:03
Data point term sent to Coder	System	05 Mar 2021 16:21:49
Data point term sent to Coder	System	05 Mar 2021 16:19:47
User entered 'Augmentin'	Lisa Macoy (b) (4) (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	Lisa Macoy (b) (4) (b) (4)	05 Mar 2021 16:18:21

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 16:21:33
User entered 'wound infection- left buttock' reason for change: New Information	System	05 Mar 2021 16:21:33
User opened query 'Data is required. Please complete.' (Site from System).	Lisa Macoy (b) (4)	05 Mar 2021 16:21:33
User entered empty.	(b) (4)	
DataPoint activated with code reason code Data required.	System	05 Mar 2021 16:19:37
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
	(b) (4)	
	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 09:22:02
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 16:43:56
User entered '875/125' reason for change: Per Query Resolution	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 16:43:49
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:48:49
User entered '875'	Lisa Macoy (b) (4) (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	Lisa Macoy (b) (4) (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	(b) (4) Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
	(b) (4)	
DataPoint activated with code reason code Data required.	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'twice daily (BID)'	(b) (4) Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	(b) (4) Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
	(b) (4)	
DataPoint activated with code reason code Data required.	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	(b) (4) Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
	(b) (4)	
DataPoint activated with code reason code Data required.	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '24 Feb 2021'	(b) (4) Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	(b) (4) Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 05:03:49
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 16:44:42
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 16:44:37
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:48:41
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	Lisa Macoy (b) (4) (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4) (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '10 Mar 2021' reason for change: New Information	(b) (4)	26 Mar 2021 16:44:37
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	(b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	(b) (4)	
	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
User entered '2'	System	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
User entered '1'	System	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:18:06
User entered '804 (804)'	System	05 Mar 2021 16:19:37
DataPoint activated with code reason code Data required.	Lisa Macoy (b) (4)	05 Mar 2021 16:18:21
DataPoint inactivated with code reason code Data not required.	Lisa Macoy (b) (4)	09 Feb 2021 14:06:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
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)	12 Apr 2021 07:49:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:49:55
Data point term sent to Coder	System	09 Apr 2021 16:23:20
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:22:29
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 17:24:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 17:24:50
Data point term sent to Coder	System	11 Mar 2021 17:24:15
Data point term sent to Coder	System	10 Mar 2021 19:33:18
Data point term sent to Coder	System	10 Mar 2021 18:26:37
User entered 'Vancomycin'	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 18:26:36

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 18:26:36

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:23:22
Signature has been broken.	Lisa Macoy (b) (4)	09 Apr 2021 16:22:29
User entered 'SEPSIS/wound infection left buttock'	(b) (4)	
reason for change: Per Query Resolution	Lisa Macoy (b) (4)	09 Apr 2021 16:22:29
User signature succeeded.	(b) (4)	
	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Sepsis' reason for change: Per Query	(b) (4)	
Resolution	Lisa Macoy (b) (4)	11 Mar 2021 17:23:39
User entered 'Wound infection left buttock'	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:32:20
User entered '2000' reason for change: Data Entry Error	System	10 Mar 2021 19:32:20
User opened query 'Data is required. Please complete.' (Site from System).	Lisa Macoy (b) (4)	10 Mar 2021 19:32:20
User entered empty.	(b) (4)	
	System	10 Mar 2021 18:26:36
	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 19:32:20
User entered 'Other (OTHER)'	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty; reason for change Data Entry Error	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 19:32:20
User entered 'unk'	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	10 Mar 2021 19:32:20
User entered 'unknown (UNKNOWN)'	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 18:26:36

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:32:20
User entered 'Intravenous Drip (INTRAVENOUS DRIP)' reason for change: New Information	System	10 Mar 2021 19:32:20
User opened query 'Data is required. Please complete.' (Site from System).	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
User entered empty.	System	10 Mar 2021 18:26:36
	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 18:26:36

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	10 Mar 2021 19:32:20
User entered '19 Feb 2021' reason for change: New Information	Lisa Macoy (b) (4)	10 Mar 2021 19:32:20
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	10 Mar 2021 18:26:36
User entered empty.	System	10 Mar 2021 18:26:36
	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 18:26:36

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:32:20
User entered 'No (N)' reason for change: New Information	System	10 Mar 2021 19:32:20
User opened query 'Data is required. Please complete.' (Site from System).	Lisa Macoy (b) (4)	10 Mar 2021 19:32:20
User entered empty.	(b) (4)	
	System	10 Mar 2021 18:26:36
	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '19 Feb 2021' reason for change: New Information	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 19:32:20
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:32:20
User entered 'No (N)' reason for change: Data Entry Error	System	10 Mar 2021 19:32:20
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	10 Mar 2021 19:32:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Mar 2021 18:26:36
	Lisa Macoy (b) (4)	10 Mar 2021 18:26:36
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
User entered empty.	System	10 Mar 2021 18:26:36

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
User entered empty.	System	10 Mar 2021 18:26:36

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:10
User entered empty.	System	10 Mar 2021 18:26:36

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:04:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:04:54
Data point term sent to Coder	System	09 Apr 2021 16:23:20
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:22:48
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:44:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:44:41
Data point term sent to Coder	System	10 Mar 2021 19:44:31
Data point term sent to Coder	System	10 Mar 2021 19:40:27
User entered 'Rocephin'	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 19:39:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:24:15
Signature has been broken.	Lisa Macoy (b) (4)	09 Apr 2021 16:22:48
User entered 'WOUND INFECTION LEFT BUTTOCK/Sepsis' reason for change: Per Query Resolution	(b) (4) Lisa Macoy (b) (4)	09 Apr 2021 16:22:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'wound infection left buttock' reason for change: Data Entry Error	(b) (4) Lisa Macoy (b) (4)	10 Mar 2021 19:44:27
User entered 'infected bedsore'	Lisa Macoy (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'l'	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 19:39:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'g (g)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 19:39:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 19:39:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '19 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '23 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
User entered '1'	System	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
User entered '1'	System	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:37
User entered '804 (804)'	System	10 Mar 2021 19:39:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
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)	19 Apr 2021 08:08:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:08:32
Data point term sent to Coder	System	16 Apr 2021 13:47:15
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:46:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 17:26:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 17:26:04
Data point term sent to Coder	System	11 Mar 2021 17:25:17
Data point term sent to Coder	System	10 Mar 2021 19:44:31
User entered 'Vancomycin'	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:25
User closed query 'please check if should be both Wound infection left buttock and Sepsis ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:11:23
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
Query 'please check if should be both Wound infection left buttock and Sepsis ' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	16 Apr 2021 13:46:55
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 13:46:50
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 13:46:50
User entered 'SEPSIS/wound infection left buttock' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	16 Apr 2021 13:46:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User opened query 'please check if should be both Wound infection left buttock and Sepsis ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:17:35
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Sepsis' reason for change: Data Entry Error	Lisa Macoy (b) (4)	11 Mar 2021 17:24:56
User entered 'wound infection left buttock'	Lisa Macoy (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '1000'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 19:43:45
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	10 Mar 2021 19:43:45
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '21 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '24 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:25
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
User entered '1'	System	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
User entered '1'	System	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:17:02
User entered '804 (804)'	System	10 Mar 2021 19:43:45

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Mar 2021 17:25:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 17:25:36
Data point term sent to Coder	System	26 Mar 2021 17:09:34
User entered 'Glipizide'	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:09:31

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Type II Diabetes'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '5'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '28 Jan 2021'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	26 Mar 2021 17:09:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 17:09:31

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 17:09:31

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Mar 2021 17:09:31

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
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.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 21:55:00
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 Apr 2021 21:55:00
Data point term sent to Coder Coding entries removed.	System Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 21:54:42 16 Apr 2021 21:53:51
Signature has been broken.	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 21:53:51
User entered 'METOPROLOL Succinate' reason for change: New Information	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 21:53:51
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 17:26:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 17:26:27
Data point term sent to Coder User entered 'Metoprolol'	System Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:10:35 26 Mar 2021 17:10:31

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Hypertension'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'per answer for DCF for CM #21 (TOPROL-XL) dose of this drug was changed 01Jan21, Please check and update Start date and Dose for this line (Metoprolol = TOPROL-XL)' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 02:13:15
Query 'per answer for DCF for CM #21 (TOPROL-XL) dose of this drug was changed 01Jan21, Please check and update Start date and Dose for this line (Metoprolol = TOPROL-XL)' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	16 Apr 2021 21:00:31
User opened query 'per answer for DCF for CM #21 (TOPROL-XL) dose of this drug was changed 01Jan21, Please check and update Start date and Dose for this line (Metoprolol = TOPROL-XL)' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:32:08
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '50'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '14 Jan 2021'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	22 Apr 2021 14:54:12
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	22 Apr 2021 14:54:12
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	22 Apr 2021 14:54:12
	(b) (4)	
User entered '16 Apr 2021' reason for change: Data Entry Error	Lisa Macoy (b) (4)	22 Apr 2021 14:54:12
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	26 Mar 2021 17:10:31
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 17:10:31

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 17:10:31

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Mar 2021 17:10:31

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Mar 2021 14:02:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 14:02:32
Data point term sent to Coder	System	26 Mar 2021 17:14:42
Data point term sent to Coder	System	26 Mar 2021 17:12:37
User entered 'Lasix'	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:12:15

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Bilateral LEG SWELLING' reason for change: Data Entry Error	Lisa Macoy (b) (4)	26 Mar 2021 17:14:00
	(b) (4)	
User entered 'Leg swelling'	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '40'	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'as needed (PRN)'	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '14 Jan 2021'	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 17:14:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 17:14:00
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	26 Mar 2021 17:14:00
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 17:12:15
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 17:12:15
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:12:15

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:12:15

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:12:15

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:16:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:16:53
Data point term sent to Coder	System	09 Apr 2021 16:42:02
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:41:26
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:28
Data point term sent to Coder	System	26 Mar 2021 17:39:16
User entered 'Flagyl'	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:26:24
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#11) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 04:13:25
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#11) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	06 Apr 2021 15:52:12
Signature has been broken.	Lisa Macoy (b) (4) (b) (4)	06 Apr 2021 15:51:48
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	06 Apr 2021 15:51:48
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#11) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:22:49
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:00:45
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
Signature has been broken.	(b) (4)	
	Lisa Macoy (b) (4)	09 Apr 2021 16:41:26
	(b) (4)	
User entered 'SEPSIS/Wound infection left buttock'	Lisa Macoy (b) (4)	09 Apr 2021 16:41:26
reason for change: Per Query Resolution	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
	(b) (4)	
User entered 'Sepsis'	Lisa Macoy (b) (4)	26 Mar 2021 17:38:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '1000'	(b) (4)	
	Lisa Macoy (b) (4)	26 Mar 2021 17:38:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	26 Mar 2021 17:38:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'three times daily (TID)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	26 Mar 2021 17:38:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	26 Mar 2021 17:38:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '19 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '20 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 00:48:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
User entered '3'	System	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
User entered '1'	System	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:09
User entered '804 (804)'	System	26 Mar 2021 17:38:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 13:50:48
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 Apr 2021 13:50:48
Data point term sent to Coder	System	16 Apr 2021 13:49:17
User entered 'albuterol'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'wheezing'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '0.5'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'mL (mL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'as needed (PRN)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '14 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '18 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:29
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 13:49:03
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
User entered empty.	System	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
User entered empty.	System	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:18
User entered empty.	System	16 Apr 2021 13:49:03

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
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.	(b) (4) Coder Import (b) (4)	16 Apr 2021 14:02:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:02:43
Data point term sent to Coder	System	16 Apr 2021 14:01:59
User entered 'insulin Lispro'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:01:39

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered 'Type II diabetes'	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered '100/30'	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered 'IU (IU)'	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	16 Apr 2021 16:09:16
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:01:39

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered 'three times daily (TID)'	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	16 Apr 2021 16:09:16
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:01:39

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:01:39

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered '12 Sep 2020'	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	16 Apr 2021 14:01:39
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 14:01:39

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:01:39

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 14:01:39

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 15:00:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:00:47
Data point term sent to Coder	System	16 Apr 2021 14:05:03
User entered 'ipratropium'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'wheezing'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '0.5'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
User closed query 'please check with source if should be ml OR mg, correct where necessary' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 02:14:38
Query 'please check with source if should be ml OR mg, correct where necessary' answered with 'mL is correct' (Site from CRA).	Cindy Lubbers (b) (4) (b) (4)	16 Apr 2021 20:40:29
User opened query 'please check with source if should be ml OR mg, correct where necessary' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:46:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	16 Apr 2021 16:09:16
User entered 'mL (mL)'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'as needed (PRN)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 14:04:07
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '14 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '18 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
User entered empty.	System	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
User entered empty.	System	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:18
User entered empty.	System	16 Apr 2021 14:04:07

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:47
Data point term sent to Coder	System	16 Apr 2021 14:07:04
User entered 'enoxaparin'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'myocardial infarction'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '30'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 14:06:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '14 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '18 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:04
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 14:06:40
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
User entered '1'	System	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
User entered '1'	System	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:26
User entered '804 (804)'	System	16 Apr 2021 14:06:40

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
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.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 14:08:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:08:54
Data point term sent to Coder	System	16 Apr 2021 14:08:05
User entered 'hydralazine'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'hypertension'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '10'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 14:07:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '13 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 14:08:16
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Apr 2021 14:08:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Apr 2021 14:07:54
	Lisa Macoy (b) (4)	16 Apr 2021 14:07:54
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '13 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:19
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
User entered '1'	System	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
User entered '1'	System	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:28
User entered '804 (804)'	System	16 Apr 2021 14:07:54

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:15:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:15:59
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	16 Apr 2021 16:09:16
Data point term sent to Coder	System	16 Apr 2021 14:10:06
User entered 'morphine'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Myocardial infarction'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '2'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'as needed (PRN)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '12 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '13 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:54
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
User entered empty.	System	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
User entered empty.	System	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:37
User entered empty.	System	16 Apr 2021 14:09:30

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
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.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:15:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:15:01
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	16 Apr 2021 16:09:16
Data point term sent to Coder	System	16 Apr 2021 14:39:58
User entered 'milrinone'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'myocardial infarction'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '20'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'once daily (QD)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 14:38:56
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '12 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '14 Sep 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:31
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
User entered '1'	System	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
User entered '1'	System	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:16:03
User entered '804 (804)'	System	16 Apr 2021 14:38:56

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
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.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 14:56:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 14:56:00
Data point term sent to Coder	System	22 Apr 2021 14:55:19
User entered 'METOPROLOL SUCCINATE'	Lisa Macoy (b) (4) (b) (4)	22 Apr 2021 14:54:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered 'hypertension'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered '25'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	22 Apr 2021 15:17:41
User entered empty.	Lisa Macoy (b) (4) (b) (4)	22 Apr 2021 14:54:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered '16 Apr 2021'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:17:41
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	22 Apr 2021 14:54:49
	(b) (4)	

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 14:54:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 14:54:49

US3532170

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:10:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 14:54:49

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:10:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:04:50
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:40:20

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:10:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:42
User closed query 'please review date of procedure with discharge summary' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:22:17
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
Query 'please review date of procedure with discharge summary' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	16 Apr 2021 14:32:34
DataPoint Un-verified.	Lisa Macoy (b) (4)	16 Apr 2021 14:32:28
Signature has been broken.	Lisa Macoy (b) (4)	16 Apr 2021 14:32:28
User entered '8 Sep 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	16 Apr 2021 14:32:28
User opened query 'please review date of procedure with discharge summary' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 14:45:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered '6 Sep 2020'	Lisa Macoy (b) (4)	19 Oct 2020 19:40:45

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered 'CABG x 2'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:40:45

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered 'Adverse Event (AE)'	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:40:45

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:10:48

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered empty.	Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 19:40:45

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:17
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:36:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered '27 Nov 2020'	Lisa Macoy (b) (4)	22 Dec 2020 18:09:51

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:17
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:36:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered 'bedsore wound debridement'	Lisa Macoy (b) (4) (b) (4)	22 Dec 2020 18:09:51

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:17
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:36:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered 'Adverse Event (AE)'	Lisa Macoy (b) (4)	22 Dec 2020 18:09:51

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:10:48

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:17
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:36:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered empty.	Lisa Macoy (b) (4)	22 Dec 2020 18:09:51

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:10:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered '20 Jan 2021'	Lisa Macoy (b) (4)	22 Feb 2021 17:41:06

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered 'Wound vac placment'	Lisa Macoy (b) (4) (b) (4)	22 Feb 2021 17:41:06

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered 'Adverse Event (AE)'	Lisa Macoy (b) (4)	22 Feb 2021 17:41:06

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:10:48

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:42
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered empty.	Lisa Macoy (b) (4)	22 Feb 2021 17:41:06

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:10:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:04
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:45
User closed query 'Please add Hematology dd 19 and 20 Feb 21' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:33:00
Query 'Please add Hematology dd 19 and 20 Feb 21' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	09 Apr 2021 16:35:10
User opened query 'Please add Hematology dd 19 and 20 Feb 21' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:30:20
User closed query 'Please add: - Hematology dd 19 and 20 Feb 21 -CT Abdomen + Pelvis dd 19 Feb 21' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:30:20
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Query 'Please add: - Hematology dd 19 and 20 Feb 21 -CT Abdomen + Pelvis dd 19 Feb 21' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	26 Mar 2021 14:02:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:04:25
User opened query 'Please add: - Hematology dd 19 and 20 Feb 21 -CT Abdomen + Pelvis dd 19 Feb 21' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 21:04:06
User entered '21 Feb 2021'	Lisa Macoy (b) (4)	10 Mar 2021 20:25:22

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:04
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered 'blood culture'	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 20:25:22

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:04
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered 'Adverse Event (AE)'	Lisa Macoy (b) (4) (b) (4)	10 Mar 2021 20:25:22

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:10:48

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:38:04
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:04:25
User entered empty.	Lisa Macoy (b) (4)	10 Mar 2021 20:25:22
	(b) (4)	

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:10:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:10
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:48
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:28:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '19 Feb 2021'	Lisa Macoy (b) (4)	26 Mar 2021 14:02:05

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:10
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:48
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:28:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'CT of abd and pelvis with contrast'	(b) (4) Lisa Macoy (b) (4) (b) (4)	26 Mar 2021 14:02:05

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:10
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:48
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:28:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'Adverse Event (AE)'	Lisa Macoy (b) (4)	26 Mar 2021 14:02:05

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:10:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:10
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:48
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:28:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered empty.	Lisa Macoy (b) (4)	26 Mar 2021 14:02:05

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:10:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:13
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '20 Nov 2020'	Cindy Lubbers (b) (4)	08 Apr 2021 16:14:10

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:13
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Echocardiogram'	Cindy Lubbers (b) (4)	08 Apr 2021 16:14:10

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:13
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Adverse Event (AE)'	Cindy Lubbers (b) (4)	08 Apr 2021 16:14:10

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:10:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:13
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	Cindy Lubbers (b) (4)	08 Apr 2021 16:14:10

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:10:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:15
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered '19 Nov 2020'	Cindy Lubbers (b) (4)	08 Apr 2021 16:15:08

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:15
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Event monitor (wore for 2 weeks)'	Cindy Lubbers (b) (4)	08 Apr 2021 16:15:08

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:15
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered 'Adverse Event (AE)'	Cindy Lubbers (b) (4)	08 Apr 2021 16:15:08

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:10:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:15
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
User entered empty.	(b) (4) Cindy Lubbers (b) (4)	08 Apr 2021 16:15:08

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:10:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:18
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:33:15
User entered '19 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:37:28

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:18
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:33:15
User entered 'Hematology draw' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:38:42
User entered 'WOUND INFECTION/LEFT BUTTOCK/Sepsis' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:37:43
User entered 'Wound infection/Left buttock'	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:37:28

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:18
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:33:15
User entered 'Adverse Event (AE)'	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:37:28

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:10:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:18
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:33:15
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:37:28

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:10:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:24
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:33:18
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	09 Apr 2021 16:38:26
User entered '20 Feb 2021' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:38:26
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	09 Apr 2021 16:38:16
User entered '20 Feb 2020'	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:38:16

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:10:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:24
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:33:18
User entered 'Hematology draw'	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:38:16

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:10:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:24
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:33:18
User entered 'Adverse Event (AE)'	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:38:16

US3532170

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:10:48

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:14:24
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:33:18
User entered empty.	Lisa Macoy (b) (4) (b) (4)	09 Apr 2021 16:38:16

US3532170

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:10:48

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '2 Oct 2020'	(b) (4) Lisa Macoy (b) (4) (b) (4)	19 Oct 2020 14:54:50

US3532170

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:10:48

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'SAE (specify) (SAE)'	Lisa Macoy (b) (4)	19 Oct 2020 14:54:50

US3532170

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:02
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User closed query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 23:30:20
Query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' answered with 'updated' (Site from DM).	Laila Hussaini (b) (4)	19 Nov 2020 19:41:09
User entered 'SAE #1' reason for change: Data Entry Error	Laila Hussaini (b) (4)	19 Nov 2020 19:41:04
User opened query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:04:54
User entered 'myocardial infarction'	Lisa Macoy (b) (4)	19 Oct 2020 14:54:50

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:08:38
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'USA-US077-2020-MRNA-1273-P301000001'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Evan'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Anderson'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '2015 Uppergate Drive'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Atlanta'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'GA'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '30323'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:18:43
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:13:09
User entered 'US' (non-conformant).	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 16:21:36
User entered '6'	System	09 Nov 2020 11:27:54
User entered '5'	System	22 Oct 2020 19:05:35
User entered '4'	System	21 Oct 2020 15:45:44
User entered '3'	System	20 Oct 2020 12:08:48
User entered '2'	System	16 Oct 2020 19:18:59
User entered '1'	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:08:38
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'USA-US077-2020-MRNA-1273-P301000001'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Evan'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Anderson'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '2015 Uppergate Drive'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Atlanta'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'GA'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '30323'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:18:43
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:13:09
User entered 'US' (non-conformant).	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 16:21:36
User entered '6'	System	09 Nov 2020 11:27:54
User entered '5'	System	22 Oct 2020 19:05:35
User entered '4'	System	21 Oct 2020 15:45:44
User entered '3'	System	20 Oct 2020 12:08:48
User entered '2'	System	16 Oct 2020 19:18:59
User entered '1'	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '16/Sep/2020 09:50'	(b) (4) System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:18:43
User entered 'I'	(b) (4), (b) (6)	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:08:38
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'USA-US077-2020-MRNA-1273-P301000001'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Evan'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Anderson'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '2015 Uppergate Drive'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Atlanta'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'GA'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '30323'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:18:43
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:13:09
User entered 'US' (non-conformant).	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 16:21:36
User entered '6'	System	09 Nov 2020 11:27:54
User entered '5'	System	22 Oct 2020 19:05:35
User entered '4'	System	21 Oct 2020 15:45:44
User entered '3'	System	20 Oct 2020 12:08:48
User entered '2'	System	16 Oct 2020 19:18:59
User entered '1'	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '16/Oct/2020 19:18'	(b) (4) System	16 Oct 2020 19:18:59

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:19:02
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 19:18:59

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:08:38
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'USA-US077-2020-MRNA-1273-P301000001'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Evan'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Anderson'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '2015 Uppergate Drive'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Atlanta'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'GA'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '30323'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:18:43
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:13:09
User entered 'US' (non-conformant).	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 16:21:36
User entered '6'	System	09 Nov 2020 11:27:54
User entered '5'	System	22 Oct 2020 19:05:35
User entered '4'	System	21 Oct 2020 15:45:44
User entered '3'	System	20 Oct 2020 12:08:48
User entered '2'	System	16 Oct 2020 19:18:59
User entered '1'	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '20/Oct/2020 12:08'	(b) (4) System	20 Oct 2020 12:08:48

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:45:24
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 12:08:48

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:08:38
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'USA-US077-2020-MRNA-1273-P301000001'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Evan'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Anderson'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '2015 Uppergate Drive'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Atlanta'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'GA'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '30323'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:18:43
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:13:09
User entered 'US' (non-conformant).	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 16:21:36
User entered '6'	System	09 Nov 2020 11:27:54
User entered '5'	System	22 Oct 2020 19:05:35
User entered '4'	System	21 Oct 2020 15:45:44
User entered '3'	System	20 Oct 2020 12:08:48
User entered '2'	System	16 Oct 2020 19:18:59
User entered '1'	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '21/Oct/2020 15:45'	(b) (4) System	21 Oct 2020 15:45:44

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 19:05:19
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 15:45:44

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:08:38
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'USA-US077-2020-MRNA-1273-P301000001'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Evan'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Anderson'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '2015 Uppergate Drive'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Atlanta'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'GA'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '30323'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:18:43
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:13:09
User entered 'US' (non-conformant).	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 16:21:36
User entered '6'	System	09 Nov 2020 11:27:54
User entered '5'	System	22 Oct 2020 19:05:35
User entered '4'	System	21 Oct 2020 15:45:44
User entered '3'	System	20 Oct 2020 12:08:48
User entered '2'	System	16 Oct 2020 19:18:59
User entered '1'	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '22/Oct/2020 19:05'	(b) (4) System	22 Oct 2020 19:05:35

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:27:34
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 19:05:35

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:08:38
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'USA-US077-2020-MRNA-1273-P301000001'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Evan'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Anderson'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '2015 Uppergate Drive'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Atlanta'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'GA'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '30323'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:18:43
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:13:09
User entered 'US' (non-conformant).	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 16:21:36
User entered '6'	System	09 Nov 2020 11:27:54
User entered '5'	System	22 Oct 2020 19:05:35
User entered '4'	System	21 Oct 2020 15:45:44
User entered '3'	System	20 Oct 2020 12:08:48
User entered '2'	System	16 Oct 2020 19:18:59
User entered '1'	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '09/Nov/2020 06:27'	(b) (4) System	09 Nov 2020 11:27:54

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:21:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 11:27:54

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:08:38
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'USA-US077-2020-MRNA-1273-P301000001'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Yes (Y)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'No (N)'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Evan'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Anderson'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '2015 Uppergate Drive'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'Atlanta'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered 'GA'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:50:21
User entered '30323'	System	16 Sep 2020 13:29:09

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:29
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 19:18:43
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 19:18:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:13:09
User entered 'US' (non-conformant).	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 16:21:36
User entered '6'	System	09 Nov 2020 11:27:54
User entered '5'	System	22 Oct 2020 19:05:35
User entered '4'	System	21 Oct 2020 15:45:44
User entered '3'	System	20 Oct 2020 12:08:48
User entered '2'	System	16 Oct 2020 19:18:59
User entered '1'	System	16 Sep 2020 13:50:34

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:22
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
User entered '19/Apr/2021 12:21'	(b) (4) System	19 Apr 2021 16:21:36

US3532170

Folder: SAE USA-US077-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:22
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:36

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'USA-US077-2021-MRNA-1273-P301000003'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Evan'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Anderson'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '2015 Uppergate Drive'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Atlanta'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'GA'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '30323'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:16:28
User entered 'US'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Mar 2021 14:53:20
User entered '4'	System	18 Mar 2021 14:41:22
User entered '3'	System	11 Mar 2021 21:18:07
User entered '2'	System	11 Mar 2021 18:16:37
User entered '1'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'USA-US077-2021-MRNA-1273-P301000003'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Evan'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Anderson'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '2015 Uppergate Drive'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Atlanta'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'GA'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '30323'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:16:28
User entered 'US'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Mar 2021 14:53:20
User entered '4'	System	18 Mar 2021 14:41:22
User entered '3'	System	11 Mar 2021 21:18:07
User entered '2'	System	11 Mar 2021 18:16:37
User entered '1'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '23/Feb/2021 13:11'	(b) (4) System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:16:28
User entered 'I'	(b) (4), (b) (6)	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'USA-US077-2021-MRNA-1273-P301000003'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Evan'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Anderson'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '2015 Uppergate Drive'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Atlanta'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'GA'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '30323'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:16:28
User entered 'US'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Mar 2021 14:53:20
User entered '4'	System	18 Mar 2021 14:41:22
User entered '3'	System	11 Mar 2021 21:18:07
User entered '2'	System	11 Mar 2021 18:16:37
User entered '1'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '11/Mar/2021 13:16'	(b) (4) System	11 Mar 2021 18:16:37

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:17:49
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 18:16:37

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'USA-US077-2021-MRNA-1273-P301000003'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Evan'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Anderson'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '2015 Uppergate Drive'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Atlanta'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'GA'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '30323'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:16:28
User entered 'US'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Mar 2021 14:53:20
User entered '4'	System	18 Mar 2021 14:41:22
User entered '3'	System	11 Mar 2021 21:18:07
User entered '2'	System	11 Mar 2021 18:16:37
User entered '1'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '11/Mar/2021 16:18'	(b) (4) System	11 Mar 2021 21:18:07

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:40:05
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 21:18:07

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'USA-US077-2021-MRNA-1273-P301000003'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Evan'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Anderson'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '2015 Uppergate Drive'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Atlanta'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'GA'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '30323'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:16:28
User entered 'US'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Mar 2021 14:53:20
User entered '4'	System	18 Mar 2021 14:41:22
User entered '3'	System	11 Mar 2021 21:18:07
User entered '2'	System	11 Mar 2021 18:16:37
User entered '1'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '18/Mar/2021 10:41'	(b) (4) System	18 Mar 2021 14:41:22

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:53:09
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 14:41:22

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'USA-US077-2021-MRNA-1273-P301000003'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Yes (Y)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'No (N)'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Evan'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Anderson'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '2015 Uppergate Drive'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'Atlanta'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered 'GA'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:11:37
User entered '30323'	System	23 Feb 2021 18:08:51

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:16:28
User entered 'US'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Mar 2021 14:53:20
User entered '4'	System	18 Mar 2021 14:41:22
User entered '3'	System	11 Mar 2021 21:18:07
User entered '2'	System	11 Mar 2021 18:16:37
User entered '1'	System	23 Feb 2021 18:11:52

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:10:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered '29/Mar/2021 09:53'	(b) (4) System	29 Mar 2021 14:53:20

US3532170

Folder: SAE USA-US077-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:10:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:00:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:53:20