

US3062019 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:03:29

All time stamps listed in this document are displayed in GMT

US3062019

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Participant ID

US3062019

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

US3062019

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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

US3062019

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Date of Birth (MMM yyyy)	(b) (6) 1954
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

US3062019

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Date of Informed Consent (*dd MMM yyyy*) 31 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3062019

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3062019

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Were any significant conditions reported?

Yes ☒

No ☐

US3062019

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	03 AUG 2009
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)	AUG 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3062019

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	TYPER II DIABETES MELLITUS
Start date (dd MMM yyyy)	01 JAN 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062019

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	01 JAN 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062019

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	01 APR 2005
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)	APR 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3062019

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062019

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	GENERALIZED ARTHRITIS, UNSPECIFIED, NON AUTOIMMUNE
Start date (dd MMM yyyy)	01 JAN 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

US3062019

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	01 JAN 2005
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)	01 JAN 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3062019

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	RIGHT OVARIAN CYST
Start date (dd MMM yyyy)	01 JAN 2005
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)	01 JAN 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3062019

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	TOTAL LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	13 AUG 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)	13 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

US3062019

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	EDEMA BILATERAL LOWER EXTREMITIES
Start date (dd MMM yyyy)	01 JAN 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3062019

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	OSTEOARTHRITIS BILATERAL KNEES
Start date (dd MMM yyyy)	01 JAN 1969
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 1969
Start Year (derived)	1969
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062019

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062019

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Condition	ALLERGIC RHINITIS, SEASONAL
Start date (dd MMM yyyy)	01 FEB 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)	FEB 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3062019

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	16:20 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 16:20
Height (<i>xxx.x</i>)	170.0 cm
Weight (<i>xxx.x</i>)	126.8 kg
BMI (<i>xxx.x</i>)	43.87543 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)	

US3062019

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 2020

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

US3062019

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Date of assessment (*dd MMM yyyy*) 31 JUL 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*) 01 JAN 2005

Date of surgery unknown False

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

Date of last menstruation unknown False

US3062019

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3062019

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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

US3062019

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 184352

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 ☒

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Height	ND - Not Done
Weight	ND - Not Done

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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)	31 JUL 2020
Time of assessment (00:00-23:59)	16:20 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 16:20
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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)	31 JUL 2020
Time of assessment (00:00-23:59)	18:31 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 18:31
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3062019

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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.

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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) 31 JUL 2020

What was the treatment time? (00:00-23:59) 17:59 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 17:59

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

US3062019

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 JUL 2020
Collection time (00:00-23:59)	17:18 (24 HR)
Collection date and time (derived)	31 JUL 2020 17:18

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Collection date (dd MMM yyyy)			31 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:20	31 JUL 2020 17:20
Nasopharyngeal Swab 2	No		

US3062019

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 18:33

PC Open Date & Time

31 JUL 2020 18:19

PC Close Date & Time

31 JUL 2020 20:49

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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 99.3 °F

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

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

PC Time Stamp	31 JUL 2020 22:04
PC Open Date & Time	31 JUL 2020 21:44
PC Close Date & Time	01 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 21:28

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 21:02

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

98.7 °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

03 AUG 2020 20:54

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

99.7 °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

04 AUG 2020 20:57

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

05 AUG 2020 20:50

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 20:11

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 18:34

PC Open Date & Time

31 JUL 2020 18:19

PC Close Date & Time

31 JUL 2020 20:49

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

31 JUL 2020 22:05

PC Open Date & Time

31 JUL 2020 21:44

PC Close Date & Time

01 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

01 AUG 2020 21:28

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

02 AUG 2020 21:02

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

03 AUG 2020 20:55

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

04 AUG 2020 20:57

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

05 AUG 2020 20:50

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

06 AUG 2020 20:11

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 18:36
PC Open Date & Time	31 JUL 2020 18:19
PC Close Date & Time	31 JUL 2020 20:49

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 22:05
---------------	-------------------

PC Open Date & Time	31 JUL 2020 21:44
---------------------	-------------------

PC Close Date & Time	01 AUG 2020 11:59
----------------------	-------------------

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

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 ☒

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 21:29
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

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 3177

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 21:03
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 3177

EAB) (1725)

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 20:55
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

62 of 3177

EAB) (1725)

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 20:58
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 3177

EAB) (1725)

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 20:51
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

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 ☒

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 20:12
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3062019

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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

Visit date (dd MMM yyyy)	28 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	VISIT2
------------	--------

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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)	28 AUG 2020
Time of assessment (00:00-23:59)	15:27 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:27
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)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	17:21 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 17:21
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3062019

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:50 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 16:50

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

US3062019

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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

Collection date (dd MMM yyyy)	28 AUG 2020
-------------------------------	-------------

Collection time (00:00-23:59)	15:41 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	28 AUG 2020 15:41
------------------------------------	-------------------

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:43	28 AUG 2020 15:43
Nasopharyngeal Swab 2	No		

US3062019

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

98.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp 28 AUG 2020 17:24

PC Open Date & Time 28 AUG 2020 17:10

PC Close Date & Time 28 AUG 2020 19:40

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	28 AUG 2020 22:44
PC Open Date & Time	28 AUG 2020 20:35
PC Close Date & Time	29 AUG 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 19:00

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 20:41

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 21:08

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 21:45

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

02 SEP 2020 20:38

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

03 SEP 2020 21:29

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 17:25

PC Open Date & Time

28 AUG 2020 17:10

PC Close Date & Time

28 AUG 2020 19:40

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 22:44

PC Open Date & Time

28 AUG 2020 20:35

PC Close Date & Time

29 AUG 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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 ☐

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

50

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

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

Yes ☒

No ☐

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

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 19:17

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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 ☐

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

60

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

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

Yes ☒

No ☐

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

40

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 20:41

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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 ☐

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

25

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

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 21:09

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

25

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

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 21:46

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 20:39

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:30

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 17:26
PC Open Date & Time	28 AUG 2020 17:10
PC Close Date & Time	28 AUG 2020 19:40

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 22:45
PC Open Date & Time	28 AUG 2020 20:35
PC Close Date & Time	29 AUG 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

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 ☒

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:18
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

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)

104 of 3177

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:42
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

106 of 3177

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 21:09
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

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 ☒

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:46
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

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 ☒

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:39
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

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 ☒

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:30
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 04 SEP 2020 17:39

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 8
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
PC Time stamp	04 SEP 2020 17:40
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062019

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 17:40
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062019

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:14:03

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:14:03

Generated On: 09 Jun 2021 15:03:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 13:18
Temperature (xxx.x)	98.3 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:14:03

Generated On: 09 Jun 2021 15:03:29

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.

US3062019

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 SEP 2020
Collection time (00:00-23:59)	13:38 (24 HR)
Collection date and time (derived)	22 SEP 2020 13:38

US3062019

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:13:52

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 SEP 2020 12:26:06
Patient Cloud Open Date & Time	30 SEP 2020 00:01
Patient Cloud Close Date & Time	04 OCT 2020 23:59

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 OCT 2020 16:32:40

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

14 OCT 2020 09:10:32

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 07:32:35
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 08:21:17
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 106

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

No ☒

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 NOV 2020 08:39:27

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 113

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

No ☒

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 NOV 2020 20:45:13

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 08:02:42

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 17:49:32

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

06 DEC 2020 08:00:01

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

13 DEC 2020 08:43:19

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

20 DEC 2020 00:04:27

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 08:43:00

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 11:52:30

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 00:42:30
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

17 JAN 2021 12:12:05

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☒

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 JAN 2021 12:17:52

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

31 JAN 2021 12:58:05

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 FEB 2021 09:49:49

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 FEB 2021 00:02:24

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

21 FEB 2021 08:00:28

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

28 FEB 2021 14:44:03

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 04:15:41

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

14 MAR 2021 11:47:11

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 07:24:01

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

28 MAR 2021 08:56:56

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 07:31:04

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Date and time of submission

11 APR 2021 08:32:44

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Date and time of submission

18 APR 2021 08:39:06

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Date and time of submission

25 APR 2021 07:46:38

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Date and time of submission

02 MAY 2021 13:36:27

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 <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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 <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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 <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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Patient Cloud Close Date & Time	19 AUG 2021 23:59
---	-------------------

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Patient Cloud Close Date & Time	09 DEC 2021 23:59
---	-------------------

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Patient Cloud Close Date & Time	30 DEC 2021 23:59
---	-------------------

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	20 JAN 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	30 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 565

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2022 00:01
Patient Cloud Close Date & Time	17 FEB 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAR 2022 00:01
Patient Cloud Close Date & Time	31 MAR 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐
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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 <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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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"/>

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3062019

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:03:29

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		28 FEB 2021 14:44:16

US3062019

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 22:07:17

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 22:07:16

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

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

Visit date (dd MMM yyyy)	19 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	VISIT4
------------	--------

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 12:39
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

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.

US3062019

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

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

Collection date (dd MMM yyyy)	19 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	12:47 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	19 FEB 2021 12:47
------------------------------------	-------------------

US3062019

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:12:35

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 11:57:16

Generated On: 09 Jun 2021 15:03:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3062019

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 11:57:16

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062019

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3062019

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:03:29

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"/>

US3062019

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:03:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3062019

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

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

Visit date (dd MMM yyyy)	19 JAN 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
------------	---------------

US3062019

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

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

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 19 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3062019

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

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

Collection date (dd MMM yyyy)	19 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	15:20 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	19 JAN 2021 15:20
------------------------------------	-------------------

US3062019

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

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

Collection date (dd MMM yyyy)	19 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	15:11
---------------------------------	-------

Collection Date and Time (derived)	19 JAN 2021 15:11
------------------------------------	-------------------

US3062019

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 AUG 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)

334 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

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 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)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

AEID	USA-US090-2020-MRNA-1273-P30 1000003
Adverse event	CELLULITIS LEFT KNEE
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)	18 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)	11 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)	22 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	26 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

336 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

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	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

SUBJECT WAS SEEN AT SITE ON 9/22/2020 FOR VISIT 3. DURING THE VISIT, SUBJECT REPORTED CELLULITIS LEFT KNEE WHICH STARTED ON 9/18/2020. SUBJECT WAS SEEN BY HER PERSONAL DOCTOR AND STARTED ON ANTIBIOTICS ON 9/21/2020. AFTER HER SITE VISIT, SUBJECT WENT TO THE EMERGENCY ROOM FOR CELLULITIS. SUBJECT WAS ADMITTED TO HER LOCAL HOSPITAL AND WAS LATER TRANSFERRED TO A LARGER HOSPITAL. SUBJECT REPORTS SHE IS BEING GIVEN IV ANTIBIOTICS AND A SURGERY IS PLANNED FOR TOMORROW. SUBJECT IS UNSURE OF WHICH ANTIBIOTIC SHE IS BEING GIVEN AND DOES NOT KNOW WHAT SURGERY WILL BE PERFORMED. RELEASE OF RECORDS MAILED TO SUBJECT

UPDATE 109/2020 SUBJECT HAD AN X-RAY OF LEFT KNEE ON 9/22/2020 WHICH SHOWED SURGICAL CHANGES IN THE LEFT KNEE WITHOUT OSSEOUS ABNORMALITY. SUBJECT HAD CHEST X-RAYS ON 9/24/2020,

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

9/25/2020 AND 9/26/2020.
ECHOCARDIOGRAM
PERFORMED ON 9/24/2020.
COVID TEST ON 9/26/2020 WAS
NEGATIVE. UPDATE PROVIDED
10/26/2020. PER INVESTIGATOR,
SUBJECT'S STATUS STABILIZED
AT TIME OF DISCHARGE FROM
THE HOSPITAL. AFTER
DISCHARGE FROM THE
HOSPITAL, SUBJECT NO
LONGER MET THE CRITERIA
FOR SAE. STATUS UPDATED TO
RECOVERED WITH SEQUALAE
DUE TO SUBJECT CONTINUING
TO RECEIVE ANTIBIOTICS TO
TREAT CELLULITIS. DURING
HOSPITALIZATION, SUBJECT
HAD BLOOD CULTURES WHICH
INDICATED NO GROWTH
AFTER 5 DAYS. ALSO, HAD
CULTURE OF KNEE WHICH
SHOWED "NO GROWTH".
BLOOD CULTURE WAS
CONDUCTED ON 9/22/2020 AND
9/24/2020. FLUID KNEE
CULTURE WAS CONDUCTED
ON 9/22/2020 AND TISSUE KNEE
CULTURE WAS DONE ON
9/24/2020.
UPDATE ON 02/10/2021
UPDATED END DATES FOR CON
MEDS RELATED TO SAE. ALSO
UPDATED SAE FROM
RECOVERED WITH SEQUALAE

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

TO RECOVERED/RESOLVED.
NORCO STOP DATE WAS
10/11/2020 AND TYLENOL END
DATE WAS 10/11/2020.

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

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

AEID	
Adverse event	DEHYDRATION
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)	22 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)	25 SEP 2020
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)

341 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

AEID

Adverse event

LEFT KNEE ABCESS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 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)

16 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

343 of 3177

EAB) (1725)

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

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	False
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 _____	
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)	_____

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

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)	24 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)	24 SEP 2020
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)

345 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

AEID	
Adverse event	HEART MURMUR RECURRENT
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)	23 SEP 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 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)

347 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 31 Mar 2021 20:52:10

Generated On: 09 Jun 2021 15:03:29

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)	_____

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

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

Yes ☒

No ☐

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

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

350 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 JAN 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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

352 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 2019	
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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication OXYBUTYNIN PATCH

Prophylaxis Yes ☐
No ☒

Indication OVERACTIVE BLADDER

Dose per administration 3.9

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

356 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

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

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED ARTHRITIS,
UNSPECIFIED, NON
AUTOIMMUNE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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)	UN UNK 1993	
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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 175

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
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)

360 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 2000	
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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES MELLITUS

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

362 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 2000	
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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication LOVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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)

364 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 AUG 2009
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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES MELLITUS

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)

366 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 2000
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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication OXYBUTININ

Prophylaxis Yes ☐
No ☒

Indication OVERACTIVE BLADDER

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)

368 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 2005	
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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

370 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 2010	
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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication GINGER ROOT

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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)

372 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication IRON

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 65

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

374 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication LISINOPRIL

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)

376 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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)	07 AUG 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication KEFLEX

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

378 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 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) 23 SEP 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication BACTRIM DS, TRIMETHOPRIM
AND SULFAMETHOXAZOLE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 160/800

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
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 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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)	21 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)	23 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

382 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 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) 26 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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)		25 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) 29 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication LOVENOX (ENOXAPARIN SODIUM)

Prophylaxis Yes ☐
No ☒

Indication CELLUITUS LEFT KNEE

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 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 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)		23 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

388 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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)		11 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

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

390 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 1500

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
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)

392 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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)		26 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication DEHYDRATION

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)

394 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 SEP 2020		
Was this medication taken for solicited event?	Yes	<input 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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

EVERY HOUR

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

PRODUCTION RELEASE (v12.003

396 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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) 23 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 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) 23 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"/>	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 3.375

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

400 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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) 23 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

402 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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)		26 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) 26 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication DUONEB

Prophylaxis Yes ☐
No ☒

Indication ASTHMA-MILD

Dose per administration 1

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

If dose unit is Other, specify UNIT

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
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

404 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NEBULIZER	
Start date (dd MMM yyyy)	22 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)	26 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication DAPTOMYCIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003

406 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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) 26 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication LISPRO

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS II

Dose per administration 1

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

If dose unit is Other, specify UNIT

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
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

408 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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) 26 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication DEXTROMETHORPHAN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC COUGH

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

410 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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) 26 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication EDEMA BILATERAL LOWER
EXTREMITY

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)

412 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	<input 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication HYDROCODONE/ACETAMINOP
HEN 5MG/325MG

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

414 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 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)		11 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication ONDANSETRON

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)

416 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

418 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

420 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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)		24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication SUGAMMADEX

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

422 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

424 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication ROCURONIUM

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

426 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication SUCCINYLCHOLINE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 160

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication DIPRIVAN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

430 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication LIDOCAINE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

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)

432 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication SCOPOLAMINE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 1.5

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 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT KNEE

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

436 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS,
SEASONAL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

438 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

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

440 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	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 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) 25 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"/>	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication CYANOCOBALAMIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

442 of 3177

EAB) (1725)

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 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) 26 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"/>

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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)

444 of 3177

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 02 Apr 2021 20:12:32

Generated On: 09 Jun 2021 15:03:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 SEP 2020		
Was this medication taken for solicited event?	Yes	<input 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"/>

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 SEP 2020	IRRIGATION AND DEBRIDEMENT OF ABSCESS	Adverse Event	
24 SEP 2020	CHEST X-RAY	Adverse Event	
25 SEP 2020	CHEST X-RAY	Adverse Event	
26 SEP 2020	CHEST X-RAY	Adverse Event	
26 SEP 2020	ECHOCARDIOGRAM	Adverse Event	
22 SEP 2020	X-RAY, LEFT KNEE	Adverse Event	
24 SEP 2020	ECHOCARDIOGRAM	Adverse Event	
22 SEP 2020	BLOOD CULTURE	Adverse Event	
24 SEP 2020	BLOOD CULTURE	Adverse Event	
22 SEP 2020	FLUID KNEE CULTURE	Adverse Event	
24 SEP 2020	TISSUE KNEE CULTURE	Adverse Event	

US3062019

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:03:29

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3062019

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:29

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 ☐

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	25/SEP/2020 15:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	01/OCT/2020 08:31
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

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	05/OCT/2020 08:45
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

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	12/OCT/2020 11:18
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

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	20/OCT/2020 19:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	21/OCT/2020 15:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	26/OCT/2020 17:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	27/OCT/2020 09:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	03/NOV/2020 17:37
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

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Data signed: (b) (4) 02 Apr 2021 20:12:34

Generated On: 09 Jun 2021 15:03:29

SAEID	USA-US090-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	11/FEB/2021 14:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3062019 (Prod: Alliance for Multispecialty Research, LLC)

US3062019

Form: Participant Creation

Generated On: 09 Jun 2021 15:03:29

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered 'US3062019'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 21:34:06

US3062019

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	31 Jul 2020 23:03:50
	(b) (4)	

US3062019

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 21:34:07

US3062019

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	31 Jul 2020 23:03:50
	(b) (4)	

US3062019

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'SCRN'	System	31 Jul 2020 23:03:50

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 21:34:08

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '66'	Sherry Henning (b) (4)	31 Jul 2020 23:04:14
	(b) (4)	

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'YEARS'	System	31 Jul 2020 23:04:14

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '66'	System	31 Jul 2020 23:04:32

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Female (F)'	Sherry Henning (b) (4)	31 Jul 2020 23:04:14
	(b) (4)	

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sherry Henning (b) (4)	31 Jul 2020 23:04:14
	(b) (4)	

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'I'	(b) (4) Sherry Henning (b) (4) (b) (4)	31 Jul 2020 23:04:14

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	31 Jul 2020 23:04:14
	(b) (4)	

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	31 Jul 2020 23:04:14
	(b) (4)	

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) Sherry Henning (b) (4) (b) (4)	31 Jul 2020 23:04:14

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	31 Jul 2020 23:04:14
	(b) (4)	

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	31 Jul 2020 23:04:14
	(b) (4)	

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) Sherry Henning (b) (4)	31 Jul 2020 23:04:14

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	31 Jul 2020 23:04:14
	(b) (4)	

US3062019

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	31 Jul 2020 23:04:14
	(b) (4)	

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '31 Jul 2020'	Sherry Henning (b) (4)	31 Jul 2020 23:04:32
	(b) (4)	

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jul 2020'	System	31 Jul 2020 23:04:32

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2020'	System	31 Jul 2020 23:04:32

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Amendment 1 (1)'	(b) (4) Sherry Henning (b) (4) (b) (4)	31 Jul 2020 23:04:32

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	31 Jul 2020 23:04:32
	(b) (4)	

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	31 Jul 2020 23:04:32
	(b) (4)	

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	31 Jul 2020 23:04:32
	(b) (4)	

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	31 Jul 2020 23:04:32
	(b) (4)	

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 21:34:07

US3062019

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'I'	System	31 Jul 2020 23:04:42

US3062019

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	31 Jul 2020 23:04:42
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:03:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:32:29

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	01 Aug 2020 20:37:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:37:13
Data point term sent to Coder	System	01 Aug 2020 20:36:28
User entered 'hypercholesterolemia'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:35:31

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '03 Aug 2009'	marissa Mueller (b) (4)	01 Aug 2020 20:35:31
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:35:31

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:35:31
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:35:31
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:35:31

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Aug 2009'	System	01 Aug 2020 20:35:31

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2009'	System	01 Aug 2020 20:35:31

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:35:31

US3062019

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:35:31

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
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)	03 Aug 2020 17:57:05
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 17:57:05
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 21:02:57
User entered 'TYPER II DIABETES MELLITUS'	marissa Mueller (b) (4)	01 Aug 2020 21:02:27
reason for change: Data Entry Error	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:36:30
User entered 'typer II diabeties mellitus'	marissa Mueller (b) (4)	01 Aug 2020 20:36:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '01 Jan 1997'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:36:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:36:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:36:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:36:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:36:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 1997'	System	01 Aug 2020 20:36:11

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '1997'	System	01 Aug 2020 20:36:11

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:36:11

US3062019

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:36:11

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:37:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:37:13
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:36:28
User entered 'hypothyroidism'	marissa Mueller (b) (4)	01 Aug 2020 20:36:27
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 20:36:41
User entered '01 Jan 2000' reason for change: Data Entry Error	marissa Mueller (b) (4)	01 Aug 2020 20:36:41
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 20:36:27
User entered '01 2000' (non-conformant).	marissa Mueller (b) (4)	01 Aug 2020 20:36:27
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:36:27

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:36:27
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:36:27
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:36:27
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 2000'	System	01 Aug 2020 20:36:41
User entered empty.	System	01 Aug 2020 20:36:27

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2000'	System	01 Aug 2020 20:36:41
User entered empty.	System	01 Aug 2020 20:36:27

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:36:27

US3062019

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:36:27

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:39:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:39:14
Data point term sent to Coder	System	01 Aug 2020 20:38:33
User entered 'OVERACTIVE BLADDER' reason for change: Data Entry Error	marissa Mueller (b) (4)	01 Aug 2020 20:37:35
Data point term sent to Coder	System	01 Aug 2020 20:37:31
User entered 'Gastroesophageal reflux disease'	marissa Mueller (b) (4)	01 Aug 2020 20:37:05

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '01 Apr 2005' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:37:35
User entered '15 Sep 2008'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:37:05

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:37:05

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:37:05
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:37:05
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:37:05
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Apr 2005'	System	01 Aug 2020 20:37:35
User entered 'Sep 2008'	System	01 Aug 2020 20:37:05

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2005'	System	01 Aug 2020 20:37:35
User entered '2008'	System	01 Aug 2020 20:37:05

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:37:05

US3062019

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:37:05

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Aug 2020 20:39:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:39:14
Data point term sent to Coder	System	01 Aug 2020 20:38:32
User entered 'postmenopausal'	marissa Mueller (b) (4)	01 Aug 2020 20:37:53
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'un UNK 2005'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:37:53
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:37:53
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:37:53
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:37:53
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:37:53
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 2005'	System	01 Aug 2020 20:37:53

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2005'	System	01 Aug 2020 20:37:53

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:37:53

US3062019

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:37:53

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid). If this is RHEUMATOID ARTHRITIS, note that treatment is expected for this condition. Please reconcile with Con Med and Med History eCRFs as appropriate. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 09:44:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Polyarthrits, LLT: Generalized arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 23:54:41
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 23:54:41
Data point term sent to Coder	System	28 Aug 2020 19:29:44
Query 'Per DM CLR: Please specify the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid). If this is RHEUMATOID ARTHRITIS, note that treatment is expected for this condition. Please reconcile with Con Med and Med History eCRFs as appropriate. Update Med History eCRF as appropriate. ' answered with 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4) (b) (4)	28 Aug 2020 19:29:22
Coding entries removed.	Janna Martinez (b) (4) (b) (4)	28 Aug 2020 19:29:17
User entered 'GENERALIZED ARTHRITIS, unspecified, non autoimmune' reason for change: Data Entry Error	Janna Martinez (b) (4) (b) (4)	28 Aug 2020 19:29:17
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid). If this is RHEUMATOID ARTHRITIS, note that treatment is expected for this condition. Please reconcile with Con Med and Med History eCRFs as appropriate. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 09:43:29

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Polyarthritis, LLT: Generalized arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:39:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 20:39:14
Data point term sent to Coder	System	01 Aug 2020 20:38:32
User entered 'generalized arthritis'	marissa Mueller (b) (4)	01 Aug 2020 20:38:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '01 Jan 1993'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:38:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:38:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:38:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:38:11
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:38:11

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 1993'	System	01 Aug 2020 20:38:11

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '1993'	System	01 Aug 2020 20:38:11

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:38:11

US3062019

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	01 Aug 2020 20:38:11

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 09:52:53
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4) (b) (4)	28 Aug 2020 19:32:18
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 09:43:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:41:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:41:14
Data point term sent to Coder	System	01 Aug 2020 20:39:33
User entered 'hysterectomy'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:38:33

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '01 Jan 2005'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:38:33
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:38:33
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:38:33
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '01 Jan 2005'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:38:33

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:38:33
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 2005'	System	01 Aug 2020 20:38:33

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2005'	System	01 Aug 2020 20:38:33

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 2005'	System	01 Aug 2020 20:38:33

US3062019

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2005'	System	01 Aug 2020 20:38:33

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 19:32:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 19:32:41
Data point term sent to Coder	System	28 Aug 2020 19:31:46
User entered 'RIGHT OVARIAN CYST'	Janna Martinez (b) (4)	28 Aug 2020 19:31:22
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '01 Jan 2005'	Janna Martinez (b) (4)	28 Aug 2020 19:31:22
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:31:22
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	28 Aug 2020 19:31:22
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User closed query 'Per DM CLR: Please note that stop date is unexpected for reported chronic condition, if patient underwent surgery for reported condition, then please add procedure details to MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 06:48:16
Query 'Per DM CLR: Please note that stop date is unexpected for reported chronic condition, if patient underwent surgery for reported condition, then please add procedure details to MH eCRF.' answered with 'subject reports hysterectomy for this condition' (Site from DM).	marissa Mueller (b) (4) (b) (4)	14 Sep 2020 16:22:51
User opened query 'Per DM CLR: Please note that stop date is unexpected for reported chronic condition, if patient underwent surgery for reported condition, then please add procedure details to MH eCRF.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 09:09:59
User entered '01 Jan 2005'	Janna Martinez (b) (4) (b) (4)	28 Aug 2020 19:31:22

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) Janna Martinez (b) (4)	28 Aug 2020 19:31:22
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 2005'	System	28 Aug 2020 19:31:22

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2005'	System	28 Aug 2020 19:31:22

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 2005'	System	28 Aug 2020 19:31:22

US3062019

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2005'	System	28 Aug 2020 19:31:22

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:14:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:14:30
Data point term sent to Coder	System	09 Oct 2020 23:13:57
User entered 'Total Left Knee Replacement'	Jeri King (b) (4)	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '13 Aug 2019'	(b) (4) Jeri King (b) (4)	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) Jeri King (b) (4)	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:13:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 23:13:14
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	09 Oct 2020 23:13:14
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:13:09
User entered empty.	Jeri King (b) (4)	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '13 Aug 2019'	Jeri King (b) (4)	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) Jeri King (b) (4)	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Aug 2019'	System	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2019'	System	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Aug 2019'	System	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2019'	System	09 Oct 2020 23:13:09

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:15:29
Data point term sent to Coder	(b) (4)	
User entered 'Edema bilateral lower extremities'	System	09 Oct 2020 23:14:57
	Jeri King (b) (4)	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '01 Jan 2005'	(b) (4) Jeri King (b) (4)	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	Jeri King (b) (4)	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) Jeri King (b) (4)	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) Jeri King (b) (4)	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) Jeri King (b) (4)	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 2005'	System	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2005'	System	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	09 Oct 2020 23:14:10

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:17:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 23:17:41
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 23:15:58
User entered 'Osteoarthritis bilateral knees'	Jeri King (b) (4)	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '01 Jan 1969'	Jeri King (b) (4)	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	Jeri King (b) (4)	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Jeri King (b) (4)	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) Jeri King (b) (4)	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) Jeri King (b) (4)	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 1969'	System	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '1969'	System	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	09 Oct 2020 23:15:04

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:04:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:04:39
Data point term sent to Coder	System	21 Oct 2020 22:04:16
User entered 'obesity'	marissa Mueller (b) (4)	21 Oct 2020 22:03:51
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'un UNK 1970'	(b) (4) marissa Mueller (b) (4)	21 Oct 2020 22:03:51
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	21 Oct 2020 22:03:51
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	21 Oct 2020 22:03:51
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	21 Oct 2020 22:03:51
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	21 Oct 2020 22:03:51
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Jan 1970'	System	21 Oct 2020 22:03:51

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '1970'	System	21 Oct 2020 22:03:51

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	21 Oct 2020 22:03:51

US3062019

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	21 Oct 2020 22:03:51

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Dec 2020 20:48:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 20:48:57
Data point term sent to Coder	System	15 Dec 2020 20:47:34
User entered 'allergic rhinitis, seasonal'	marissa Mueller (b) (4)	15 Dec 2020 20:47:08
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '01 Feb 2008'	(b) (4) marissa Mueller (b) (4)	15 Dec 2020 20:47:08
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	15 Dec 2020 20:47:08
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	15 Dec 2020 20:47:08
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	15 Dec 2020 20:47:08
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	15 Dec 2020 20:47:08
	(b) (4)	

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'Feb 2008'	System	15 Dec 2020 20:47:08

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '2008'	System	15 Dec 2020 20:47:08

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	15 Dec 2020 20:47:08

US3062019

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered empty.	System	15 Dec 2020 20:47:08

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:40:17
	(b) (4)	

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '31 Jul 2020'	marissa Mueller (b) (4)	01 Aug 2020 20:40:17
	(b) (4)	

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '16:20'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:40:17

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered '31 Jul 2020 16:20'	System	01 Aug 2020 20:40:17

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '170.0' cm	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:40:17
DataPoint set to visible.	(b) (4) System	31 Jul 2020 23:04:42

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '126.8' kg	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:40:17
DataPoint set to visible.	(b) (4) System	31 Jul 2020 23:04:42

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
Amendment Manager: User entered '43.87543'	System	16 Sep 2020 23:40:09
User entered '43.9'	System	01 Aug 2020 20:40:17
DataPoint set to visible.	System	31 Jul 2020 23:04:42

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'kg/m2'	System	01 Aug 2020 20:40:17
DataPoint set to visible.	System	31 Jul 2020 23:04:42

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:31:11
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:58:47
	(b) (4)	
User entered '98.4' F	marissa Mueller (b) (4)	01 Aug 2020 20:40:17
	(b) (4)	

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty; reason for change Data Entry Error	(b) (4) Colton King (b) (4)	24 Aug 2020 18:58:47
User entered 'Oral (Oral)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:40:17
	(b) (4)	

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:40:17
	(b) (4)	

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:58:47
User entered '74'	(b) (4)	
	marissa Mueller (b) (4)	01 Aug 2020 20:40:17
	(b) (4)	

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'bpm'	System	01 Aug 2020 20:40:17

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Aug 2020 18:58:47
User entered '16'	marissa Mueller (b) (4)	01 Aug 2020 20:40:17
	(b) (4)	

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'breaths/min'	System	01 Aug 2020 20:40:17

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:58:47
User entered '136'	(b) (4)	
	marissa Mueller (b) (4)	01 Aug 2020 20:40:17
	(b) (4)	

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'mmHg'	System	01 Aug 2020 20:40:17

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Colton King (b) (4)	24 Aug 2020 18:58:47
User entered '85'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:40:17
	(b) (4)	

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User entered 'mmHg'	System	01 Aug 2020 20:40:17

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49

US3062019

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:58:59
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:38:47
	(b) (4)	

US3062019

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 13:02:19
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		28 Aug 2020 21:54:38
User entered '31 Jul 2020' reason for change: Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:58:59
User entered empty.	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:38:47

US3062019

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '31 Jul 2020'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:45:30
	(b) (4)	

US3062019

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:29

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:45:30
	(b) (4)	

US3062019

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:29

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User closed query 'Per DM CLR: Please verify, if 'Surgically Sterile' is more appropriate selection, as HYSTERECTOMY reported on Med History page. Please review and update all applicable eCRFs as appropriate.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 09:54:01
' (Site from DM).		
Query 'Per DM CLR: Please verify, if 'Surgically Sterile' is more appropriate selection, as HYSTERECTOMY reported on Med History page. Please review and update all applicable eCRFs as appropriate.	Colton King (b) (4) (b) (4)	28 Aug 2020 16:00:04
' answered with 'updated ' (Site from DM).		
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Colton King (b) (4) (b) (4)	28 Aug 2020 15:59:32
User opened query 'Per DM CLR: Please verify, if 'Surgically Sterile' is more appropriate selection, as HYSTERECTOMY reported on Med History page. Please review and update all applicable eCRFs as appropriate.	(b) (4), (b) (6)	28 Aug 2020 09:46:09
' (Site from DM).		
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	01 Aug 2020 20:45:36
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:45:36
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	01 Aug 2020 20:45:30
User entered empty.	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:45:30

US3062019

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:29

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:45:30
	(b) (4)	

US3062019

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:29

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '01 Jan 2005' reason for change: Data Entry Error	Colton King (b) (4)	28 Aug 2020 15:59:32
User entered empty.	(b) (4)	
	marissa Mueller (b) (4)	01 Aug 2020 20:45:30
	(b) (4)	

US3062019

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:29

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:45:30
	(b) (4)	

US3062019

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty; reason for change Data Entry Error	(b) (4) Colton King (b) (4)	28 Aug 2020 15:59:32
User entered '01 Jan 2005'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:45:30
	(b) (4)	

US3062019

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:29

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:45:30
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:46:31

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

[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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

[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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	04 Aug 2020 23:32:35
User entered '1' reason for change: Data Entry Error	marissa Mueller (b) (4)	04 Aug 2020 23:32:35
	(b) (4)	
User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	01 Aug 2020 20:46:31
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:46:31

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

[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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:46:31

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '0'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:01:49
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:46:31
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	31 Jul 2020 23:05:10
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '31 Jul 2020'	Sherry Henning (b) (4)	31 Jul 2020 23:05:10
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	31 Jul 2020 23:05:10
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'VISIT1'	System	31 Jul 2020 23:05:10

US3062019

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 22:34:46

US3062019

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:29

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:34:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:34:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 22:34:46
User entered '184352' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 22:34:46

US3062019

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 22:34:46

US3062019

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:29

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:44:03
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:29

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:44:03
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:44:03
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:44:03
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:44:03
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:59:10
User entered '170.0' cm	(b) (4)	
	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:59:10
User entered '126.8' kg	(b) (4)	
	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:59:10
User entered '170.0' cm	(b) (4)	
	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:59:10
User entered '126.8' kg	(b) (4)	
	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User accepted default value 'Pre-Dose (PREDOSE)'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '31 Jul 2020'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '16:20'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered '31 Jul 2020 16:20'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '98.4' F	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Oral (Oral)'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '74'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'bpm'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '16'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'breaths/min'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '136'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'mmHg'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '85'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'mmHg'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:59:10
User entered '170.0' cm	(b) (4)	
	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 18:59:10
	(b) (4)	
User entered '126.8' kg	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User accepted default value 'Post-Dose (POSTDOSE)'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '31 Jul 2020'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 05:22:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'DATA CORRECT AS ENTERED' (Site from System).	Janna Martinez (b) (4)	02 Aug 2020 21:49:39
	(b) (4)	
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		01 Aug 2020 20:42:59
User entered '18:31'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered '31 Jul 2020 18:31'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '97.5' F	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Oral (Oral)'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '69'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'bpm'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '16'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'breaths/min'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '128'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'mmHg'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '78'	marissa Mueller (b) (4)	01 Aug 2020 20:42:59
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'mmHg'	System	01 Aug 2020 20:42:59

US3062019

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	24 Aug 2020 19:00:52
	(b) (4)	
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:40:26
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty; reason for change Data Entry Error	Colton King (b) (4)	24 Aug 2020 19:00:52
	(b) (4)	
User entered '31 Jul 2020'	marissa Mueller (b) (4)	01 Aug 2020 20:40:26
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	31 Jul 2020 23:05:48
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) Sherry Henning (b) (4)	31 Jul 2020 23:05:48

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) Sherry Henning (b) (4)	31 Jul 2020 23:05:48

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 23:05:48

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '31 Jul 2020'	Sherry Henning (b) (4)	31 Jul 2020 23:05:48
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '17:59'	Sherry Henning (b) (4)	31 Jul 2020 23:05:48
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered '31 Jul 2020 17:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Sherry Henning (b) (4)	31 Jul 2020 23:05:48
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'ONCE'	System	31 Jul 2020 23:05:48

US3062019

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 23:05:48

US3062019

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:43:35
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '31 Jul 2020'	marissa Mueller (b) (4)	01 Aug 2020 20:43:35
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '17:18'	marissa Mueller (b) (4)	01 Aug 2020 20:43:35
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered '31 Jul 2020 17:18'	System	01 Aug 2020 20:43:35

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:03:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '31 Jul 2020'	marissa Mueller (b) (4)	01 Aug 2020 20:43:45
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	marissa Mueller (b) (4)	01 Aug 2020 20:43:45
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:43:45
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:29

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '17:20'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:43:45
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered '31 Jul 2020 17:20'	System	01 Aug 2020 20:43:45

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	marissa Mueller (b) (4)	01 Aug 2020 20:43:45
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:43:45
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:43:45
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered empty.	System	01 Aug 2020 20:43:45

US3062019

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Aug 2020 20:40:39
	(b) (4)	

US3062019

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'I'	System	01 Aug 2020 20:40:39

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:33:07', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e5c46ca7-a41e-4d49-b60b-2a18947e6e52'	System	31 Jul 2020 23:33:48
User entered 'Yes (Y)'	System	31 Jul 2020 23:33:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:33:17', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e5c46ca7-a41e-4d49-b60b-2a18947e6e52' User entered '97.5'	System	31 Jul 2020 23:33:48
	System	31 Jul 2020 23:33:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:33:36', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e5c46ca7-a41e-4d49-b60b-2a18947e6e52'	System	31 Jul 2020 23:33:48
User entered 'No (N)'	System	31 Jul 2020 23:33:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:33:47', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e5c46ca7-a41e-4d49-b60b-2a18947e6e52'	System	31 Jul 2020 23:33:48
User entered '31 Jul 2020 18:33'	System	31 Jul 2020 23:33:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Jul 2020 18:19'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Jul 2020 20:49'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:04:23', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a228c3ba-0db9-4413-8947-933a8e361632'	System	01 Aug 2020 03:04:48
User entered 'Yes (Y)'	System	01 Aug 2020 03:04:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:04:29', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a228c3ba-0db9-4413-8947-933a8e361632' User entered '99.3'	System	01 Aug 2020 03:04:48
	System	01 Aug 2020 03:04:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:04:36', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a228c3ba-0db9-4413-8947-933a8e361632'	System	01 Aug 2020 03:04:48
User entered 'No (N)'	System	01 Aug 2020 03:04:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:04:46', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a228c3ba-0db9-4413-8947-933a8e361632' User entered '31 Jul 2020 22:04'	System	01 Aug 2020 03:04:48
	System	01 Aug 2020 03:04:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Jul 2020 21:44'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 2'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:27:57', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5bbdbdd4-48f8-4914-b206-58253ae6b622'	System	02 Aug 2020 02:28:19
User entered 'Yes (Y)'	System	02 Aug 2020 02:28:19

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:04', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5bbdbdd4-48f8-4914-b206-58253ae6b622' User entered '98.8'	System	02 Aug 2020 02:28:19
	System	02 Aug 2020 02:28:19

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:09', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5bbdbdd4-48f8-4914-b206-58253ae6b622'	System	02 Aug 2020 02:28:19
User entered 'No (N)'	System	02 Aug 2020 02:28:19

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:15', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5bbdbdd4-48f8-4914-b206-58253ae6b622'	System	02 Aug 2020 02:28:19
User entered '01 Aug 2020 21:28'	System	02 Aug 2020 02:28:19

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 3'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:01:49', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '0ddea902-330a-4118-8d96-5dce7aed7661' User entered 'Yes (Y)'	System	03 Aug 2020 02:02:06
	System	03 Aug 2020 02:02:06

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:01:54', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '0ddea902-330a-4118-8d96-5dce7aed7661' User entered '98.5'	System	03 Aug 2020 02:02:06
	System	03 Aug 2020 02:02:06

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:01:58', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '0ddea902-330a-4118-8d96-5dce7aed7661' User entered 'No (N)'	System	03 Aug 2020 02:02:06
	System	03 Aug 2020 02:02:06

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:03', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '0ddea902-330a-4118-8d96-5dce7aed7661' User entered '02 Aug 2020 21:02'	System	03 Aug 2020 02:02:06
	System	03 Aug 2020 02:02:06

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 4'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:54:21', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'cf385600-b357-43b0-8d2c-8edb25e63838' User entered 'Yes (Y)'	System	04 Aug 2020 01:54:40
	System	04 Aug 2020 01:54:40

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:54:28', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'cf385600-b357-43b0-8d2c-8edb25e63838' User entered '98.7'	System	04 Aug 2020 01:54:40
	System	04 Aug 2020 01:54:40

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:54:31', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'cf385600-b357-43b0-8d2c-8edb25e63838'	System	04 Aug 2020 01:54:40
User entered 'No (N)'	System	04 Aug 2020 01:54:40

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:54:37', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'cf385600-b357-43b0-8d2c-8edb25e63838' User entered '03 Aug 2020 20:54'	System	04 Aug 2020 01:54:40
	System	04 Aug 2020 01:54:40

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 5'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b7315c84-dd64-4772-9746-72e02b94a715'	System	05 Aug 2020 01:57:40
User entered 'Yes (Y)'	System	05 Aug 2020 01:57:40

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:30', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b7315c84-dd64-4772-9746-72e02b94a715' User entered '99.7'	System	05 Aug 2020 01:57:40
	System	05 Aug 2020 01:57:40

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:33', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b7315c84-dd64-4772-9746-72e02b94a715'	System	05 Aug 2020 01:57:40
User entered 'No (N)'	System	05 Aug 2020 01:57:40

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:38', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b7315c84-dd64-4772-9746-72e02b94a715' User entered '04 Aug 2020 20:57'	System	05 Aug 2020 01:57:40
	System	05 Aug 2020 01:57:40

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 6'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:10', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd968561e-40f5-4f72-aa4a-e05eedc6ba63'	System	06 Aug 2020 01:50:27
User entered 'Yes (Y)'	System	06 Aug 2020 01:50:27

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:16', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd968561e-40f5-4f72-aa4a-e05eedc6ba63' User entered '98.7'	System	06 Aug 2020 01:50:27
	System	06 Aug 2020 01:50:27

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:23', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd968561e-40f5-4f72-aa4a-e05eedc6ba63'	System	06 Aug 2020 01:50:27
User entered 'No (N)'	System	06 Aug 2020 01:50:27

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:26', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd968561e-40f5-4f72-aa4a-e05eedc6ba63'	System	06 Aug 2020 01:50:27
User entered '05 Aug 2020 20:50'	System	06 Aug 2020 01:50:27

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 7'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:11:30', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '99d6abef-80a3-401f-8f7e-5fdb45501d5a' User entered 'Yes (Y)'	System	07 Aug 2020 01:11:44
	System	07 Aug 2020 01:11:44

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:11:36', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '99d6abef-80a3-401f-8f7e-5fdb45501d5a' User entered '98.6'	System	07 Aug 2020 01:11:44
	System	07 Aug 2020 01:11:44

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:11:40', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '99d6abef-80a3-401f-8f7e-5fdb45501d5a'	System	07 Aug 2020 01:11:44
User entered 'No (N)'	System	07 Aug 2020 01:11:44

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:11:42', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '99d6abef-80a3-401f-8f7e-5fdb45501d5a' User entered '06 Aug 2020 20:11'	System	07 Aug 2020 01:11:44
	System	07 Aug 2020 01:11:44

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:34:23', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '9d48a71b-0ab6-4915-a6f7-1d776f2ffb95'	System	31 Jul 2020 23:35:01
User entered 'None (1)'	System	31 Jul 2020 23:35:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:34:28', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '9d48a71b-0ab6-4915-a6f7-1d776f2ffb95'	System	31 Jul 2020 23:35:01
User entered 'No (N)'	System	31 Jul 2020 23:35:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:34:39', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '9d48a71b-0ab6-4915-a6f7-1d776f2ffb95'	System	31 Jul 2020 23:35:01
User entered 'No (N)'	System	31 Jul 2020 23:35:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:34:51', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '9d48a71b-0ab6-4915-a6f7-1d776f2ffb95'	System	31 Jul 2020 23:35:01
User entered 'None (1)'	System	31 Jul 2020 23:35:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:34:58', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '9d48a71b-0ab6-4915-a6f7-1d776f2ffb95'	System	31 Jul 2020 23:35:01
User entered '31 Jul 2020 18:34'	System	31 Jul 2020 23:35:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Jul 2020 18:19'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Jul 2020 20:49'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:04:52', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2c165f07-2aa3-409a-b781-e3657486dc75'	System	01 Aug 2020 03:05:15
User entered 'None (1)'	System	01 Aug 2020 03:05:15

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:04:56', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2c165f07-2aa3-409a-b781-e3657486dc75' User entered 'No (N)'	System	01 Aug 2020 03:05:15
	System	01 Aug 2020 03:05:15

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:01', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2c165f07-2aa3-409a-b781-e3657486dc75' User entered 'No (N)'	System	01 Aug 2020 03:05:15
	System	01 Aug 2020 03:05:15

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:05', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2c165f07-2aa3-409a-b781-e3657486dc75'	System	01 Aug 2020 03:05:15
User entered 'None (1)'	System	01 Aug 2020 03:05:15

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:13', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2c165f07-2aa3-409a-b781-e3657486dc75' User entered '31 Jul 2020 22:05'	System	01 Aug 2020 03:05:15
	System	01 Aug 2020 03:05:15

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Jul 2020 21:44'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 2'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:28', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ddbbee3-5484-402e-829a-4d6e4aed2f80'	System	02 Aug 2020 02:28:51
User entered 'None (1)'	System	02 Aug 2020 02:28:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:32', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ddbbee3-5484-402e-829a-4d6e4aed2f80' User entered 'No (N)'	System	02 Aug 2020 02:28:51
	System	02 Aug 2020 02:28:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:36', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ddbbee3-5484-402e-829a-4d6e4aed2f80' User entered 'No (N)'	System	02 Aug 2020 02:28:51
	System	02 Aug 2020 02:28:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:40', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ddbbee3-5484-402e-829a-4d6e4aed2f80' User entered 'None (1)'	System	02 Aug 2020 02:28:51
	System	02 Aug 2020 02:28:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:47', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ddbbee3-5484-402e-829a-4d6e4aed2f80' User entered '01 Aug 2020 21:28'	System	02 Aug 2020 02:28:51
	System	02 Aug 2020 02:28:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 3'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:25', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '84613c46-82d8-48ac-bcba-0e04256fe58f' User entered 'None (1)'	System	03 Aug 2020 02:02:43
	System	03 Aug 2020 02:02:43

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:28', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '84613c46-82d8-48ac-bcba-0e04256fe58f' User entered 'No (N)'	System	03 Aug 2020 02:02:43
	System	03 Aug 2020 02:02:43

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:31', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '84613c46-82d8-48ac-bcba-0e04256fe58f' User entered 'No (N)'	System	03 Aug 2020 02:02:43
	System	03 Aug 2020 02:02:43

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:36', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '84613c46-82d8-48ac-bcba-0e04256fe58f' User entered 'None (1)'	System	03 Aug 2020 02:02:43
	System	03 Aug 2020 02:02:43

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:40', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '84613c46-82d8-48ac-bcba-0e04256fe58f' User entered '02 Aug 2020 21:02'	System	03 Aug 2020 02:02:43
	System	03 Aug 2020 02:02:43

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 4'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:54:44', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'bd4b2d35-156e-41b4-a95c-b218f52eb74f' User entered 'None (1)'	System	04 Aug 2020 01:55:05
	System	04 Aug 2020 01:55:05

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:54:48', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'bd4b2d35-156e-41b4-a95c-b218f52eb74f' User entered 'No (N)'	System	04 Aug 2020 01:55:05
	System	04 Aug 2020 01:55:05

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:54:51', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'bd4b2d35-156e-41b4-a95c-b218f52eb74f' User entered 'No (N)'	System	04 Aug 2020 01:55:05
	System	04 Aug 2020 01:55:05

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:54:58', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'bd4b2d35-156e-41b4-a95c-b218f52eb74f' User entered 'None (1)'	System	04 Aug 2020 01:55:05
	System	04 Aug 2020 01:55:05

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:55:02', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'bd4b2d35-156e-41b4-a95c-b218f52eb74f' User entered '03 Aug 2020 20:55'	System	04 Aug 2020 01:55:05
	System	04 Aug 2020 01:55:05

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 5'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:43', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '454cc7f3-2cd0-4607-a821-6b0e57429f43' User entered 'None (1)'	System	05 Aug 2020 01:58:01
	System	05 Aug 2020 01:58:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:46', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '454cc7f3-2cd0-4607-a821-6b0e57429f43' User entered 'No (N)'	System	05 Aug 2020 01:58:01
	System	05 Aug 2020 01:58:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:49', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '454cc7f3-2cd0-4607-a821-6b0e57429f43' User entered 'No (N)'	System	05 Aug 2020 01:58:01
	System	05 Aug 2020 01:58:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:52', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '454cc7f3-2cd0-4607-a821-6b0e57429f43' User entered 'None (1)'	System	05 Aug 2020 01:58:01
	System	05 Aug 2020 01:58:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:55', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '454cc7f3-2cd0-4607-a821-6b0e57429f43' User entered '04 Aug 2020 20:57'	System	05 Aug 2020 01:58:01
	System	05 Aug 2020 01:58:01

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 6'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:31', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'dbc5586f-90e9-4c98-a9b5-4fc34486e8a6'	System	06 Aug 2020 01:50:51
User entered 'None (1)'	System	06 Aug 2020 01:50:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:39', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'dbc5586f-90e9-4c98-a9b5-4fc34486e8a6'	System	06 Aug 2020 01:50:51
User entered 'No (N)'	System	06 Aug 2020 01:50:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:42', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'dbc5586f-90e9-4c98-a9b5-4fc34486e8a6'	System	06 Aug 2020 01:50:51
User entered 'No (N)'	System	06 Aug 2020 01:50:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:46', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'dbc5586f-90e9-4c98-a9b5-4fc34486e8a6'	System	06 Aug 2020 01:50:51
User entered 'None (1)'	System	06 Aug 2020 01:50:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:48', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'dbc5586f-90e9-4c98-a9b5-4fc34486e8a6'	System	06 Aug 2020 01:50:51
User entered '05 Aug 2020 20:50'	System	06 Aug 2020 01:50:51

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 7'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:11:47', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'c7a7ff14-6abd-42b3-969a-a0cad7bf0050' User entered 'None (1)'	System	07 Aug 2020 01:12:02
	System	07 Aug 2020 01:12:02

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:11:50', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'c7a7ff14-6abd-42b3-969a-a0cad7bf0050' User entered 'No (N)'	System	07 Aug 2020 01:12:02
	System	07 Aug 2020 01:12:02

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:11:53', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'c7a7ff14-6abd-42b3-969a-a0cad7bf0050'	System	07 Aug 2020 01:12:02
User entered 'No (N)'	System	07 Aug 2020 01:12:02

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:11:55', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'c7a7ff14-6abd-42b3-969a-a0cad7bf0050' User entered 'None (1)'	System	07 Aug 2020 01:12:02
	System	07 Aug 2020 01:12:02

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:11:59', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'c7a7ff14-6abd-42b3-969a-a0cad7bf0050' User entered '06 Aug 2020 20:11'	System	07 Aug 2020 01:12:02
	System	07 Aug 2020 01:12:02

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:35:06', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd0b6f919-4804-49cd-b6bd-8087250c4be1' User entered 'None (0)'	System	31 Jul 2020 23:36:20
	System	31 Jul 2020 23:36:20

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:35:17', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd0b6f919-4804-49cd-b6bd-8087250c4be1' User entered 'None (0)'	System	31 Jul 2020 23:36:20
	System	31 Jul 2020 23:36:20

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:35:26', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd0b6f919-4804-49cd-b6bd-8087250c4be1' User entered 'None (0)'	System	31 Jul 2020 23:36:20
	System	31 Jul 2020 23:36:20

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:35:32', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd0b6f919-4804-49cd-b6bd-8087250c4be1' User entered 'None (0)'	System	31 Jul 2020 23:36:20
	System	31 Jul 2020 23:36:20

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:35:41', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd0b6f919-4804-49cd-b6bd-8087250c4be1' User entered 'None (0)'	System	31 Jul 2020 23:36:20
	System	31 Jul 2020 23:36:20

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:35:48', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd0b6f919-4804-49cd-b6bd-8087250c4be1' User entered 'None (0)'	System	31 Jul 2020 23:36:20
	System	31 Jul 2020 23:36:20

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:35:55', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd0b6f919-4804-49cd-b6bd-8087250c4be1' User entered 'No (N)'	System	31 Jul 2020 23:36:20
	System	31 Jul 2020 23:36:20

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T18:36:16', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd0b6f919-4804-49cd-b6bd-8087250c4be1' User entered '31 Jul 2020 18:36'	System	31 Jul 2020 23:36:20
	System	31 Jul 2020 23:36:20

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Jul 2020 18:19'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Jul 2020 20:49'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3ad158ce-f07d-4cd6-b5dd-6c063ba33d6d' User entered 'None (0)'	System	01 Aug 2020 03:05:56
	System	01 Aug 2020 03:05:56

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:23', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3ad158ce-f07d-4cd6-b5dd-6c063ba33d6d' User entered 'None (0)'	System	01 Aug 2020 03:05:56
	System	01 Aug 2020 03:05:56

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:27', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3ad158ce-f07d-4cd6-b5dd-6c063ba33d6d' User entered 'None (0)'	System	01 Aug 2020 03:05:56
	System	01 Aug 2020 03:05:56

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:31', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3ad158ce-f07d-4cd6-b5dd-6c063ba33d6d' User entered 'None (0)'	System	01 Aug 2020 03:05:56
	System	01 Aug 2020 03:05:56

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:34', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3ad158ce-f07d-4cd6-b5dd-6c063ba33d6d' User entered 'None (0)'	System	01 Aug 2020 03:05:56
	System	01 Aug 2020 03:05:56

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:37', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3ad158ce-f07d-4cd6-b5dd-6c063ba33d6d' User entered 'None (0)'	System	01 Aug 2020 03:05:56
	System	01 Aug 2020 03:05:56

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:45', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3ad158ce-f07d-4cd6-b5dd-6c063ba33d6d' User entered 'No (N)'	System	01 Aug 2020 03:05:56
	System	01 Aug 2020 03:05:56

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-07-31T22:05:52', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3ad158ce-f07d-4cd6-b5dd-6c063ba33d6d' User entered '31 Jul 2020 22:05'	System	01 Aug 2020 03:05:56
	System	01 Aug 2020 03:05:56

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Jul 2020 21:44'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 2'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:51', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8aa6d812-5e61-47fa-aab3-efceba69818d' User entered 'None (0)'	System	02 Aug 2020 02:29:22
	System	02 Aug 2020 02:29:22

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:55', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8aa6d812-5e61-47fa-aab3-efceba69818d' User entered 'None (0)'	System	02 Aug 2020 02:29:22
	System	02 Aug 2020 02:29:22

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:28:58', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8aa6d812-5e61-47fa-aab3-efceba69818d' User entered 'None (0)'	System	02 Aug 2020 02:29:22
	System	02 Aug 2020 02:29:22

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:29:01', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8aa6d812-5e61-47fa-aab3-efceba69818d' User entered 'None (0)'	System	02 Aug 2020 02:29:22
	System	02 Aug 2020 02:29:22

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:29:05', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8aa6d812-5e61-47fa-aab3-efceba69818d' User entered 'None (0)'	System	02 Aug 2020 02:29:22
	System	02 Aug 2020 02:29:22

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:29:08', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8aa6d812-5e61-47fa-aab3-efceba69818d' User entered 'None (0)'	System	02 Aug 2020 02:29:22
	System	02 Aug 2020 02:29:22

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:29:12', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8aa6d812-5e61-47fa-aab3-efceba69818d' User entered 'No (N)'	System	02 Aug 2020 02:29:22
	System	02 Aug 2020 02:29:22

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-01T21:29:20', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8aa6d812-5e61-47fa-aab3-efceba69818d' User entered '01 Aug 2020 21:29'	System	02 Aug 2020 02:29:22
	System	02 Aug 2020 02:29:22

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 3'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:45', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '13c27190-2354-4592-a801-e20060f73402' User entered 'None (0)'	System	03 Aug 2020 02:03:14
	System	03 Aug 2020 02:03:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:47', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '13c27190-2354-4592-a801-e20060f73402' User entered 'None (0)'	System	03 Aug 2020 02:03:14
	System	03 Aug 2020 02:03:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:52', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '13c27190-2354-4592-a801-e20060f73402' User entered 'None (0)'	System	03 Aug 2020 02:03:14
	System	03 Aug 2020 02:03:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:56', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '13c27190-2354-4592-a801-e20060f73402' User entered 'None (0)'	System	03 Aug 2020 02:03:14
	System	03 Aug 2020 02:03:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:02:59', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '13c27190-2354-4592-a801-e20060f73402' User entered 'None (0)'	System	03 Aug 2020 02:03:14
	System	03 Aug 2020 02:03:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:03:02', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '13c27190-2354-4592-a801-e20060f73402' User entered 'None (0)'	System	03 Aug 2020 02:03:14
	System	03 Aug 2020 02:03:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:03:07', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '13c27190-2354-4592-a801-e20060f73402' User entered 'No (N)'	System	03 Aug 2020 02:03:14
	System	03 Aug 2020 02:03:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-02T21:03:12', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '13c27190-2354-4592-a801-e20060f73402' User entered '02 Aug 2020 21:03'	System	03 Aug 2020 02:03:14
	System	03 Aug 2020 02:03:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 4'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:55:06', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fc856df-b364-4fc2-b214-586d42931995' User entered 'None (0)'	System	04 Aug 2020 01:55:38
	System	04 Aug 2020 01:55:38

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:55:09', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fc856df-b364-4fc2-b214-586d42931995' User entered 'None (0)'	System	04 Aug 2020 01:55:38
	System	04 Aug 2020 01:55:38

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:55:13', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fc856df-b364-4fc2-b214-586d42931995' User entered 'None (0)'	System	04 Aug 2020 01:55:38
	System	04 Aug 2020 01:55:38

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:55:18', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fc856df-b364-4fc2-b214-586d42931995' User entered 'None (0)'	System	04 Aug 2020 01:55:38
	System	04 Aug 2020 01:55:38

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:55:21', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fc856df-b364-4fc2-b214-586d42931995' User entered 'None (0)'	System	04 Aug 2020 01:55:38
	System	04 Aug 2020 01:55:38

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:55:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fc856df-b364-4fc2-b214-586d42931995' User entered 'None (0)'	System	04 Aug 2020 01:55:38
	System	04 Aug 2020 01:55:38

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:55:30', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fc856df-b364-4fc2-b214-586d42931995'	System	04 Aug 2020 01:55:38
User entered 'No (N)'	System	04 Aug 2020 01:55:38

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-03T20:55:35', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fc856df-b364-4fc2-b214-586d42931995' User entered '03 Aug 2020 20:55'	System	04 Aug 2020 01:55:38
	System	04 Aug 2020 01:55:38

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 5'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:57:59', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '7504e180-8c6b-402a-a370-528890fad4f9' User entered 'None (0)'	System	05 Aug 2020 01:58:25
	System	05 Aug 2020 01:58:25

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:58:01', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '7504e180-8c6b-402a-a370-528890fad4f9' User entered 'None (0)'	System	05 Aug 2020 01:58:25
	System	05 Aug 2020 01:58:25

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:58:03', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '7504e180-8c6b-402a-a370-528890fad4f9' User entered 'None (0)'	System	05 Aug 2020 01:58:25
	System	05 Aug 2020 01:58:25

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:58:06', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '7504e180-8c6b-402a-a370-528890fad4f9' User entered 'None (0)'	System	05 Aug 2020 01:58:25
	System	05 Aug 2020 01:58:25

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:58:08', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '7504e180-8c6b-402a-a370-528890fad4f9' User entered 'None (0)'	System	05 Aug 2020 01:58:25
	System	05 Aug 2020 01:58:25

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:58:10', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '7504e180-8c6b-402a-a370-528890fad4f9' User entered 'None (0)'	System	05 Aug 2020 01:58:25
	System	05 Aug 2020 01:58:25

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:58:14', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '7504e180-8c6b-402a-a370-528890fad4f9' User entered 'No (N)'	System	05 Aug 2020 01:58:25
	System	05 Aug 2020 01:58:25

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-04T20:58:23', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '7504e180-8c6b-402a-a370-528890fad4f9'	System	05 Aug 2020 01:58:25
User entered '04 Aug 2020 20:58'	System	05 Aug 2020 01:58:25

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 6'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:52', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2a3923f8-3a84-4a09-87fb-79353c3cddf4' User entered 'None (0)'	System	06 Aug 2020 01:51:14
	System	06 Aug 2020 01:51:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:55', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2a3923f8-3a84-4a09-87fb-79353c3cddf4' User entered 'None (0)'	System	06 Aug 2020 01:51:14
	System	06 Aug 2020 01:51:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:50:58', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2a3923f8-3a84-4a09-87fb-79353c3cddf4' User entered 'None (0)'	System	06 Aug 2020 01:51:14
	System	06 Aug 2020 01:51:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:51:01', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2a3923f8-3a84-4a09-87fb-79353c3cddf4' User entered 'None (0)'	System	06 Aug 2020 01:51:14
	System	06 Aug 2020 01:51:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:51:03', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2a3923f8-3a84-4a09-87fb-79353c3cddf4' User entered 'None (0)'	System	06 Aug 2020 01:51:14
	System	06 Aug 2020 01:51:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:51:06', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2a3923f8-3a84-4a09-87fb-79353c3cddf4' User entered 'None (0)'	System	06 Aug 2020 01:51:14
	System	06 Aug 2020 01:51:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:51:11', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2a3923f8-3a84-4a09-87fb-79353c3cddf4'	System	06 Aug 2020 01:51:14
User entered 'No (N)'	System	06 Aug 2020 01:51:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-05T20:51:13', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '2a3923f8-3a84-4a09-87fb-79353c3cddf4' User entered '05 Aug 2020 20:51'	System	06 Aug 2020 01:51:14
	System	06 Aug 2020 01:51:14

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 7'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:12:03', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b29477b5-9d0c-415d-80e4-a8c9d821f514' User entered 'None (0)'	System	07 Aug 2020 01:12:23
	System	07 Aug 2020 01:12:23

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:12:05', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b29477b5-9d0c-415d-80e4-a8c9d821f514' User entered 'None (0)'	System	07 Aug 2020 01:12:23
	System	07 Aug 2020 01:12:23

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:12:07', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b29477b5-9d0c-415d-80e4-a8c9d821f514' User entered 'None (0)'	System	07 Aug 2020 01:12:23
	System	07 Aug 2020 01:12:23

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:12:10', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b29477b5-9d0c-415d-80e4-a8c9d821f514' User entered 'None (0)'	System	07 Aug 2020 01:12:23
	System	07 Aug 2020 01:12:23

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:12:12', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b29477b5-9d0c-415d-80e4-a8c9d821f514' User entered 'None (0)'	System	07 Aug 2020 01:12:23
	System	07 Aug 2020 01:12:23

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:12:14', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b29477b5-9d0c-415d-80e4-a8c9d821f514' User entered 'None (0)'	System	07 Aug 2020 01:12:23
	System	07 Aug 2020 01:12:23

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:12:18', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b29477b5-9d0c-415d-80e4-a8c9d821f514' User entered 'No (N)'	System	07 Aug 2020 01:12:23
	System	07 Aug 2020 01:12:23

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-06T20:12:21', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b29477b5-9d0c-415d-80e4-a8c9d821f514' User entered '06 Aug 2020 20:12'	System	07 Aug 2020 01:12:23
	System	07 Aug 2020 01:12:23

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 23:05:48

US3062019

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 15:40:25
	(b) (4)	

US3062019

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '7 Aug 2020' reason for change: Data Entry Error	Sherry Henning (b) (4)	09 Aug 2020 15:40:37
	(b) (4)	
User entered '8 Aug 2020'	Sherry Henning (b) (4)	09 Aug 2020 15:40:25
	(b) (4)	

US3062019

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	09 Aug 2020 15:40:25
	(b) (4)	

US3062019

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	09 Aug 2020 15:40:25
	(b) (4)	

US3062019

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	09 Aug 2020 15:42:38
	(b) (4)	

US3062019

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'I'	System	09 Aug 2020 15:42:38

US3062019

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	20 Aug 2020 16:32:09
	(b) (4)	

US3062019

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '15 Aug 2020'	Janna Martinez (b) (4)	20 Aug 2020 16:32:09
	(b) (4)	

US3062019

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	20 Aug 2020 16:32:09
	(b) (4)	

US3062019

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	20 Aug 2020 16:32:09
	(b) (4)	

US3062019

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	20 Aug 2020 16:31:30
	(b) (4)	

US3062019

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'I'	System	20 Aug 2020 16:31:30

US3062019

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	21 Aug 2020 20:15:56
	(b) (4)	

US3062019

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '21 Aug 2020'	Janna Martinez (b) (4)	21 Aug 2020 20:15:56
	(b) (4)	

US3062019

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	21 Aug 2020 20:15:56
	(b) (4)	

US3062019

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	21 Aug 2020 20:15:56
	(b) (4)	

US3062019

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	21 Aug 2020 20:16:01
	(b) (4)	

US3062019

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'I'	System	21 Aug 2020 20:16:01

US3062019

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Brianna Burton (b) (4)	28 Aug 2020 21:54:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '28 Aug 2020'	Brianna Burton (b) (4)	28 Aug 2020 21:54:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Clinic (Clinic)'	Brianna Burton (b) (4)	28 Aug 2020 21:54:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'VISIT2'	System	28 Aug 2020 21:54:38

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User accepted default value 'Pre-Dose (PREDOSE)'	Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '28 Aug 2020'	Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '15:27'	Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered '28 Aug 2020 15:27'	System	29 Aug 2020 15:11:49

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '98.5' F	Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Oral (Oral)'	(b) (4) Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '82'	Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'bpm'	System	29 Aug 2020 15:11:49

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'breaths/min'	System	29 Aug 2020 15:11:49

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '121'	Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'mmHg'	System	29 Aug 2020 15:11:49

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '75'	Janna Martinez (b) (4)	29 Aug 2020 15:11:49
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'mmHg'	System	29 Aug 2020 15:11:49

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User accepted default value 'Post-Dose (POSTDOSE)'	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '28 Aug 2020'	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '17:21'	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered '28 Aug 2020 17:21'	System	29 Aug 2020 15:12:36

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '98.8' F	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '75'	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'bpm'	System	29 Aug 2020 15:12:36

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'breaths/min'	System	29 Aug 2020 15:12:36

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '129'	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'mmHg'	System	29 Aug 2020 15:12:36

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '86'	Janna Martinez (b) (4)	29 Aug 2020 15:12:36
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'mmHg'	System	29 Aug 2020 15:12:36

US3062019

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	29 Aug 2020 15:12:45
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '28 Aug 2020'	Janna Martinez (b) (4)	29 Aug 2020 15:12:45
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Brianna Burton (b) (4)	28 Aug 2020 21:54:59
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	Brianna Burton (b) (4)	28 Aug 2020 21:54:59
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) Brianna Burton (b) (4) (b) (4)	28 Aug 2020 21:54:59

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 21:54:59

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '28 Aug 2020'	Brianna Burton (b) (4)	28 Aug 2020 21:54:59
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '16:50'	Brianna Burton (b) (4)	28 Aug 2020 21:54:59
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered '28 Aug 2020 16:50'	System	28 Aug 2020 21:54:59

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Brianna Burton (b) (4)	28 Aug 2020 21:54:59
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'ONCE'	System	28 Aug 2020 21:54:59

US3062019

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 21:54:59

US3062019

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	29 Aug 2020 15:13:24
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '28 Aug 2020'	Janna Martinez (b) (4)	29 Aug 2020 15:13:24
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '15:41'	Janna Martinez (b) (4)	29 Aug 2020 15:13:24
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered '28 Aug 2020 15:41'	System	29 Aug 2020 15:13:24

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:03:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '28 Aug 2020'	Janna Martinez (b) (4)	29 Aug 2020 15:13:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Janna Martinez (b) (4)	29 Aug 2020 15:13:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	29 Aug 2020 15:13:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:29

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '15:43'	Janna Martinez (b) (4)	29 Aug 2020 15:13:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered '28 Aug 2020 15:43'	System	29 Aug 2020 15:13:38

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Janna Martinez (b) (4)	29 Aug 2020 15:13:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	29 Aug 2020 15:13:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered empty.	(b) (4) Janna Martinez (b) (4)	29 Aug 2020 15:13:38
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered empty.	System	29 Aug 2020 15:13:38

US3062019

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	29 Aug 2020 15:13:41
	(b) (4)	

US3062019

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'I'	System	29 Aug 2020 15:13:41

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:24:33', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '94d73055-7801-484b-b7d3-b56008075aae'	System	28 Aug 2020 22:24:57
User entered 'Yes (Y)'	System	28 Aug 2020 22:24:57

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:24:39', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '94d73055-7801-484b-b7d3-b56008075aae' User entered '98.8'	System	28 Aug 2020 22:24:57
	System	28 Aug 2020 22:24:57

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:24:44', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '94d73055-7801-484b-b7d3-b56008075aae'	System	28 Aug 2020 22:24:57
User entered 'No (N)'	System	28 Aug 2020 22:24:57

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:24:56', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '94d73055-7801-484b-b7d3-b56008075aae' User entered '28 Aug 2020 17:24'	System	28 Aug 2020 22:24:57
	System	28 Aug 2020 22:24:57

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '28 Aug 2020 17:10'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '28 Aug 2020 19:40'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:44:23', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '248caa85-f6cf-48c7-bdff-0636fdbd62d3'	System	29 Aug 2020 03:44:40
User entered 'Yes (Y)'	System	29 Aug 2020 03:44:40

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:44:28', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '248caa85-f6cf-48c7-bdff-0636fdbd62d3' User entered '98.3'	System	29 Aug 2020 03:44:40
	System	29 Aug 2020 03:44:40

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:44:31', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '248caa85-f6cf-48c7-bdff-0636fdbd62d3'	System	29 Aug 2020 03:44:40
User entered 'No (N)'	System	29 Aug 2020 03:44:40

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:44:39', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '248caa85-f6cf-48c7-bdff-0636fdbd62d3'	System	29 Aug 2020 03:44:40
User entered '28 Aug 2020 22:44'	System	29 Aug 2020 03:44:40

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '28 Aug 2020 20:35'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 2'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T18:59:58', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b239202e-1dc4-4fce-b17b-babfad8414d1' User entered 'Yes (Y)'	System	30 Aug 2020 00:00:15
	System	30 Aug 2020 00:00:15

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:00:04', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b239202e-1dc4-4fce-b17b-babfad8414d1' User entered '98.3'	System	30 Aug 2020 00:00:15
	System	30 Aug 2020 00:00:15

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:00:08', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b239202e-1dc4-4fce-b17b-babfad8414d1' User entered 'No (N)'	System	30 Aug 2020 00:00:15
	System	30 Aug 2020 00:00:15

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:00:11', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b239202e-1dc4-4fce-b17b-babfad8414d1' User entered '29 Aug 2020 19:00'	System	30 Aug 2020 00:00:15
	System	30 Aug 2020 00:00:15

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 3'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:40:55', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '19e7e321-520e-4c3a-8646-14a974ba4e4d' User entered 'Yes (Y)'	System	31 Aug 2020 01:41:11
	System	31 Aug 2020 01:41:11

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:40:59', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '19e7e321-520e-4c3a-8646-14a974ba4e4d' User entered '99.2'	System	31 Aug 2020 01:41:11
	System	31 Aug 2020 01:41:11

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:02', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '19e7e321-520e-4c3a-8646-14a974ba4e4d' User entered 'No (N)'	System	31 Aug 2020 01:41:11
	System	31 Aug 2020 01:41:11

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:07', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '19e7e321-520e-4c3a-8646-14a974ba4e4d' User entered '30 Aug 2020 20:41'	System	31 Aug 2020 01:41:11
	System	31 Aug 2020 01:41:11

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 4'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:08:22', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '719fd286-2254-40a6-9e77-117fd0f61319' User entered 'Yes (Y)'	System	01 Sep 2020 02:08:34
	System	01 Sep 2020 02:08:34

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:08:26', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '719fd286-2254-40a6-9e77-117fd0f61319' User entered '99.0'	System	01 Sep 2020 02:08:34
	System	01 Sep 2020 02:08:34

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:08:29', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '719fd286-2254-40a6-9e77-117fd0f61319' User entered 'No (N)'	System	01 Sep 2020 02:08:34
	System	01 Sep 2020 02:08:34

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:08:32', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '719fd286-2254-40a6-9e77-117fd0f61319' User entered '31 Aug 2020 21:08'	System	01 Sep 2020 02:08:34
	System	01 Sep 2020 02:08:34

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 5'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:45:20', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f43dc94f-79f6-4779-b5c7-582b718f2186'	System	02 Sep 2020 02:45:38
User entered 'Yes (Y)'	System	02 Sep 2020 02:45:38

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:45:25', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f43dc94f-79f6-4779-b5c7-582b718f2186' User entered '98.6'	System	02 Sep 2020 02:45:38
	System	02 Sep 2020 02:45:38

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:45:29', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f43dc94f-79f6-4779-b5c7-582b718f2186'	System	02 Sep 2020 02:45:38
User entered 'No (N)'	System	02 Sep 2020 02:45:38

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:45:32', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f43dc94f-79f6-4779-b5c7-582b718f2186'	System	02 Sep 2020 02:45:38
User entered '01 Sep 2020 21:45'	System	02 Sep 2020 02:45:38

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 6'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:38:14', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8fc6c3fe-8914-44e9-aa6b-0e3ae7963248' User entered 'Yes (Y)'	System	03 Sep 2020 01:38:31
	System	03 Sep 2020 01:38:31

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:38:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8fc6c3fe-8914-44e9-aa6b-0e3ae7963248' User entered '98.9'	System	03 Sep 2020 01:38:31
	System	03 Sep 2020 01:38:31

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:38:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8fc6c3fe-8914-44e9-aa6b-0e3ae7963248'	System	03 Sep 2020 01:38:31
User entered 'No (N)'	System	03 Sep 2020 01:38:31

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:38:28', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8fc6c3fe-8914-44e9-aa6b-0e3ae7963248' User entered '02 Sep 2020 20:38'	System	03 Sep 2020 01:38:31
	System	03 Sep 2020 01:38:31

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 7'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:29:34', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '939dfeaa-ba24-48b5-b72b-e14328ac1143' User entered 'Yes (Y)'	System	04 Sep 2020 02:29:51
	System	04 Sep 2020 02:29:51

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:29:40', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '939dfeaa-ba24-48b5-b72b-e14328ac1143' User entered '98.7'	System	04 Sep 2020 02:29:51
	System	04 Sep 2020 02:29:51

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:29:44', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '939dfeaa-ba24-48b5-b72b-e14328ac1143'	System	04 Sep 2020 02:29:51
User entered 'No (N)'	System	04 Sep 2020 02:29:51

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:29:48', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '939dfeaa-ba24-48b5-b72b-e14328ac1143' User entered '03 Sep 2020 21:29'	System	04 Sep 2020 02:29:51
	System	04 Sep 2020 02:29:51

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:25:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd3315ae3-1888-4a9b-9b44-e8c3e64e02da' User entered 'None (1)'	System	28 Aug 2020 22:25:43
	System	28 Aug 2020 22:25:43

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:25:26', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd3315ae3-1888-4a9b-9b44-e8c3e64e02da' User entered 'No (N)'	System	28 Aug 2020 22:25:43
	System	28 Aug 2020 22:25:43

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:25:35', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd3315ae3-1888-4a9b-9b44-e8c3e64e02da' User entered 'No (N)'	System	28 Aug 2020 22:25:43
	System	28 Aug 2020 22:25:43

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:25:38', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd3315ae3-1888-4a9b-9b44-e8c3e64e02da' User entered 'None (1)'	System	28 Aug 2020 22:25:43
	System	28 Aug 2020 22:25:43

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:25:42', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'd3315ae3-1888-4a9b-9b44-e8c3e64e02da' User entered '28 Aug 2020 17:25'	System	28 Aug 2020 22:25:43
	System	28 Aug 2020 22:25:43

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '28 Aug 2020 17:10'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '28 Aug 2020 19:40'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:44:44', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '420e7a9d-6ff9-487e-8e92-6d3421a8e7cc'	System	29 Aug 2020 03:45:02
User entered 'None (1)'	System	29 Aug 2020 03:45:02

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:44:47', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '420e7a9d-6ff9-487e-8e92-6d3421a8e7cc'	System	29 Aug 2020 03:45:02
User entered 'No (N)'	System	29 Aug 2020 03:45:02

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:44:50', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '420e7a9d-6ff9-487e-8e92-6d3421a8e7cc'	System	29 Aug 2020 03:45:02
User entered 'No (N)'	System	29 Aug 2020 03:45:02

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:44:53', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '420e7a9d-6ff9-487e-8e92-6d3421a8e7cc' User entered 'None (1)'	System	29 Aug 2020 03:45:02
	System	29 Aug 2020 03:45:02

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:44:56', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '420e7a9d-6ff9-487e-8e92-6d3421a8e7cc' User entered '28 Aug 2020 22:44'	System	29 Aug 2020 03:45:02
	System	29 Aug 2020 03:45:02

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '28 Aug 2020 20:35'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 2'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:16:21', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8785f744-f4d8-432a-bc58-28dd71965979'	System	30 Aug 2020 00:17:57
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 00:17:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:16:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8785f744-f4d8-432a-bc58-28dd71965979'	System	30 Aug 2020 00:17:57
User entered 'Yes (Y)'	System	30 Aug 2020 00:17:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:16:31', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8785f744-f4d8-432a-bc58-28dd71965979'	System	30 Aug 2020 00:17:57
User entered '50'	System	30 Aug 2020 00:17:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:16:37', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8785f744-f4d8-432a-bc58-28dd71965979'	System	30 Aug 2020 00:17:57
User entered 'Yes (Y)'	System	30 Aug 2020 00:17:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:17:45', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8785f744-f4d8-432a-bc58-28dd71965979' User entered '10'	System	30 Aug 2020 00:17:57
	System	30 Aug 2020 00:17:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:17:03', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8785f744-f4d8-432a-bc58-28dd71965979'	System	30 Aug 2020 00:17:57
User entered 'None (1)'	System	30 Aug 2020 00:17:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:17:53', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8785f744-f4d8-432a-bc58-28dd71965979'	System	30 Aug 2020 00:17:57
User entered '29 Aug 2020 19:17'	System	30 Aug 2020 00:17:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 3'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5db6bfc7-681c-4520-8aeb-3a4b0a29d781' User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 01:41:57
	System	31 Aug 2020 01:41:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:23', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5db6bfc7-681c-4520-8aeb-3a4b0a29d781' User entered 'Yes (Y)'	System	31 Aug 2020 01:41:57
	System	31 Aug 2020 01:41:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:32', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5db6bfc7-681c-4520-8aeb-3a4b0a29d781' User entered '60'	System	31 Aug 2020 01:41:57
	System	31 Aug 2020 01:41:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:35', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5db6bfc7-681c-4520-8aeb-3a4b0a29d781' User entered 'Yes (Y)'	System	31 Aug 2020 01:41:57
	System	31 Aug 2020 01:41:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:41', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5db6bfc7-681c-4520-8aeb-3a4b0a29d781' User entered '40'	System	31 Aug 2020 01:41:57
	System	31 Aug 2020 01:41:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:47', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5db6bfc7-681c-4520-8aeb-3a4b0a29d781' User entered 'None (1)'	System	31 Aug 2020 01:41:57
	System	31 Aug 2020 01:41:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:54', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '5db6bfc7-681c-4520-8aeb-3a4b0a29d781' User entered '30 Aug 2020 20:41'	System	31 Aug 2020 01:41:57
	System	31 Aug 2020 01:41:57

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 4'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:08:37', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a0b851f8-21bc-4290-aa10-1cc13e99c723'	System	01 Sep 2020 02:09:11
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 02:09:11

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:08:40', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a0b851f8-21bc-4290-aa10-1cc13e99c723'	System	01 Sep 2020 02:09:11
User entered 'Yes (Y)'	System	01 Sep 2020 02:09:11

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:08:52', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a0b851f8-21bc-4290-aa10-1cc13e99c723' User entered '25'	System	01 Sep 2020 02:09:11
	System	01 Sep 2020 02:09:11

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:08:57', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a0b851f8-21bc-4290-aa10-1cc13e99c723'	System	01 Sep 2020 02:09:11
User entered 'Yes (Y)'	System	01 Sep 2020 02:09:11

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:02', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a0b851f8-21bc-4290-aa10-1cc13e99c723' User entered '20'	System	01 Sep 2020 02:09:11
	System	01 Sep 2020 02:09:11

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:06', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a0b851f8-21bc-4290-aa10-1cc13e99c723'	System	01 Sep 2020 02:09:11
User entered 'None (1)'	System	01 Sep 2020 02:09:11

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:09', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a0b851f8-21bc-4290-aa10-1cc13e99c723' User entered '31 Aug 2020 21:09'	System	01 Sep 2020 02:09:11
	System	01 Sep 2020 02:09:11

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 5'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:45:37', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'db52b710-eea7-43be-b33c-fa8c8132e806'	System	02 Sep 2020 02:46:17
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 02:46:17

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:45:40', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'db52b710-eea7-43be-b33c-fa8c8132e806'	System	02 Sep 2020 02:46:17
User entered 'Yes (Y)'	System	02 Sep 2020 02:46:17

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:45:47', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'db52b710-eea7-43be-b33c-fa8c8132e806' User entered '25'	System	02 Sep 2020 02:46:17
	System	02 Sep 2020 02:46:17

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'db52b710-eea7-43be-b33c-fa8c8132e806' User entered 'Yes (Y)'	System	02 Sep 2020 02:46:17
	System	02 Sep 2020 02:46:17

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:07', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'db52b710-eea7-43be-b33c-fa8c8132e806'	System	02 Sep 2020 02:46:17
User entered '20'	System	02 Sep 2020 02:46:17

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:10', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'db52b710-eea7-43be-b33c-fa8c8132e806'	System	02 Sep 2020 02:46:17
User entered 'None (1)'	System	02 Sep 2020 02:46:17

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:15', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'db52b710-eea7-43be-b33c-fa8c8132e806'	System	02 Sep 2020 02:46:17
User entered '01 Sep 2020 21:46'	System	02 Sep 2020 02:46:17

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 6'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:38:46', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fa45217-0aec-4a95-b712-a0dc8811bd10'	System	03 Sep 2020 01:39:18
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:38:50', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fa45217-0aec-4a95-b712-a0dc8811bd10' User entered 'No (N)'	System	03 Sep 2020 01:39:18
	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:38:54', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fa45217-0aec-4a95-b712-a0dc8811bd10' User entered 'Yes (Y)'	System	03 Sep 2020 01:39:18
	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:38:59', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fa45217-0aec-4a95-b712-a0dc8811bd10' User entered '10'	System	03 Sep 2020 01:39:18
	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:03', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fa45217-0aec-4a95-b712-a0dc8811bd10' User entered 'None (1)'	System	03 Sep 2020 01:39:18
	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:14', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4fa45217-0aec-4a95-b712-a0dc8811bd10'	System	03 Sep 2020 01:39:18
User entered '02 Sep 2020 20:39'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 7'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:29:55', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a38b1c56-5444-4b23-abf4-37e63e0bc712'	System	04 Sep 2020 02:30:14
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 02:30:14

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:29:58', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a38b1c56-5444-4b23-abf4-37e63e0bc712' User entered 'No (N)'	System	04 Sep 2020 02:30:14
	System	04 Sep 2020 02:30:14

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:01', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a38b1c56-5444-4b23-abf4-37e63e0bc712'	System	04 Sep 2020 02:30:14
User entered 'Yes (Y)'	System	04 Sep 2020 02:30:14

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:06', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a38b1c56-5444-4b23-abf4-37e63e0bc712' User entered '10'	System	04 Sep 2020 02:30:14
	System	04 Sep 2020 02:30:14

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:09', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a38b1c56-5444-4b23-abf4-37e63e0bc712'	System	04 Sep 2020 02:30:14
User entered 'None (1)'	System	04 Sep 2020 02:30:14

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:12', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a38b1c56-5444-4b23-abf4-37e63e0bc712'	System	04 Sep 2020 02:30:14
User entered '03 Sep 2020 21:30'	System	04 Sep 2020 02:30:14

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:25:56', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '10930c9a-c296-4f6b-8adf-0ce6eb99d026' User entered 'None (0)'	System	28 Aug 2020 22:26:22
	System	28 Aug 2020 22:26:22

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:25:59', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '10930c9a-c296-4f6b-8adf-0ce6eb99d026' User entered 'None (0)'	System	28 Aug 2020 22:26:22
	System	28 Aug 2020 22:26:22

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:26:02', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '10930c9a-c296-4f6b-8adf-0ce6eb99d026' User entered 'None (0)'	System	28 Aug 2020 22:26:22
	System	28 Aug 2020 22:26:22

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:26:05', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '10930c9a-c296-4f6b-8adf-0ce6eb99d026' User entered 'None (0)'	System	28 Aug 2020 22:26:22
	System	28 Aug 2020 22:26:22

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:26:08', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '10930c9a-c296-4f6b-8adf-0ce6eb99d026' User entered 'None (0)'	System	28 Aug 2020 22:26:22
	System	28 Aug 2020 22:26:22

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:26:11', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '10930c9a-c296-4f6b-8adf-0ce6eb99d026' User entered 'None (0)'	System	28 Aug 2020 22:26:22
	System	28 Aug 2020 22:26:22

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:26:15', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '10930c9a-c296-4f6b-8adf-0ce6eb99d026' User entered 'No (N)'	System	28 Aug 2020 22:26:22
	System	28 Aug 2020 22:26:22

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T17:26:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '10930c9a-c296-4f6b-8adf-0ce6eb99d026' User entered '28 Aug 2020 17:26'	System	28 Aug 2020 22:26:22
	System	28 Aug 2020 22:26:22

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '28 Aug 2020 17:10'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '28 Aug 2020 19:40'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:45:05', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '91a7ef45-564e-4d7e-985b-6069a3be900f' User entered 'None (0)'	System	29 Aug 2020 03:45:28
	System	29 Aug 2020 03:45:28

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:45:08', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '91a7ef45-564e-4d7e-985b-6069a3be900f' User entered 'None (0)'	System	29 Aug 2020 03:45:28
	System	29 Aug 2020 03:45:28

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:45:10', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '91a7ef45-564e-4d7e-985b-6069a3be900f' User entered 'None (0)'	System	29 Aug 2020 03:45:28
	System	29 Aug 2020 03:45:28

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:45:13', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '91a7ef45-564e-4d7e-985b-6069a3be900f' User entered 'None (0)'	System	29 Aug 2020 03:45:28
	System	29 Aug 2020 03:45:28

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:45:16', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '91a7ef45-564e-4d7e-985b-6069a3be900f' User entered 'None (0)'	System	29 Aug 2020 03:45:28
	System	29 Aug 2020 03:45:28

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:45:18', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '91a7ef45-564e-4d7e-985b-6069a3be900f' User entered 'None (0)'	System	29 Aug 2020 03:45:28
	System	29 Aug 2020 03:45:28

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:45:22', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '91a7ef45-564e-4d7e-985b-6069a3be900f' User entered 'No (N)'	System	29 Aug 2020 03:45:28
	System	29 Aug 2020 03:45:28

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-28T22:45:25', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '91a7ef45-564e-4d7e-985b-6069a3be900f' User entered '28 Aug 2020 22:45'	System	29 Aug 2020 03:45:28
	System	29 Aug 2020 03:45:28

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '28 Aug 2020 20:35'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 2'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:17:57', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '77b8912b-857e-49cc-9851-32b392603177' User entered 'None (0)'	System	30 Aug 2020 00:18:33
	System	30 Aug 2020 00:18:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:18:01', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '77b8912b-857e-49cc-9851-32b392603177' User entered 'None (0)'	System	30 Aug 2020 00:18:33
	System	30 Aug 2020 00:18:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:18:05', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '77b8912b-857e-49cc-9851-32b392603177' User entered 'None (0)'	System	30 Aug 2020 00:18:33
	System	30 Aug 2020 00:18:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:18:09', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '77b8912b-857e-49cc-9851-32b392603177' User entered 'None (0)'	System	30 Aug 2020 00:18:33
	System	30 Aug 2020 00:18:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:18:12', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '77b8912b-857e-49cc-9851-32b392603177' User entered 'None (0)'	System	30 Aug 2020 00:18:33
	System	30 Aug 2020 00:18:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:18:14', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '77b8912b-857e-49cc-9851-32b392603177' User entered 'None (0)'	System	30 Aug 2020 00:18:33
	System	30 Aug 2020 00:18:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:18:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '77b8912b-857e-49cc-9851-32b392603177' User entered 'No (N)'	System	30 Aug 2020 00:18:33
	System	30 Aug 2020 00:18:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-29T19:18:26', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '77b8912b-857e-49cc-9851-32b392603177' User entered '29 Aug 2020 19:18'	System	30 Aug 2020 00:18:33
	System	30 Aug 2020 00:18:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 3'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:41:58', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a2f897df-ed27-4aba-9150-b334c839df92' User entered 'None (0)'	System	31 Aug 2020 01:42:30
	System	31 Aug 2020 01:42:30

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:42:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a2f897df-ed27-4aba-9150-b334c839df92'	System	31 Aug 2020 01:42:30
User entered 'None (0)'	System	31 Aug 2020 01:42:30

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:42:03', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a2f897df-ed27-4aba-9150-b334c839df92'	System	31 Aug 2020 01:42:30
User entered 'None (0)'	System	31 Aug 2020 01:42:30

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:42:06', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a2f897df-ed27-4aba-9150-b334c839df92'	System	31 Aug 2020 01:42:30
User entered 'None (0)'	System	31 Aug 2020 01:42:30

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:42:09', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a2f897df-ed27-4aba-9150-b334c839df92'	System	31 Aug 2020 01:42:30
User entered 'None (0)'	System	31 Aug 2020 01:42:30

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:42:11', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a2f897df-ed27-4aba-9150-b334c839df92'	System	31 Aug 2020 01:42:30
User entered 'None (0)'	System	31 Aug 2020 01:42:30

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:42:20', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a2f897df-ed27-4aba-9150-b334c839df92'	System	31 Aug 2020 01:42:30
User entered 'No (N)'	System	31 Aug 2020 01:42:30

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-30T20:42:26', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a2f897df-ed27-4aba-9150-b334c839df92'	System	31 Aug 2020 01:42:30
User entered '30 Aug 2020 20:42'	System	31 Aug 2020 01:42:30

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 4'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:12', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23f262b7-1f29-43a3-82ce-8eb8b22f0279' User entered 'None (0)'	System	01 Sep 2020 02:09:33
	System	01 Sep 2020 02:09:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:14', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23f262b7-1f29-43a3-82ce-8eb8b22f0279' User entered 'None (0)'	System	01 Sep 2020 02:09:33
	System	01 Sep 2020 02:09:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:16', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23f262b7-1f29-43a3-82ce-8eb8b22f0279' User entered 'None (0)'	System	01 Sep 2020 02:09:33
	System	01 Sep 2020 02:09:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23f262b7-1f29-43a3-82ce-8eb8b22f0279' User entered 'None (0)'	System	01 Sep 2020 02:09:33
	System	01 Sep 2020 02:09:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:21', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23f262b7-1f29-43a3-82ce-8eb8b22f0279' User entered 'None (0)'	System	01 Sep 2020 02:09:33
	System	01 Sep 2020 02:09:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:23', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23f262b7-1f29-43a3-82ce-8eb8b22f0279' User entered 'None (0)'	System	01 Sep 2020 02:09:33
	System	01 Sep 2020 02:09:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:26', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23f262b7-1f29-43a3-82ce-8eb8b22f0279' User entered 'No (N)'	System	01 Sep 2020 02:09:33
	System	01 Sep 2020 02:09:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-08-31T21:09:29', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23f262b7-1f29-43a3-82ce-8eb8b22f0279' User entered '31 Aug 2020 21:09'	System	01 Sep 2020 02:09:33
	System	01 Sep 2020 02:09:33

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 5'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '570863f1-b10b-4c41-b075-89ce21ecf3b8' User entered 'None (0)'	System	02 Sep 2020 02:46:40
	System	02 Sep 2020 02:46:40

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:21', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '570863f1-b10b-4c41-b075-89ce21ecf3b8' User entered 'None (0)'	System	02 Sep 2020 02:46:40
	System	02 Sep 2020 02:46:40

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '570863f1-b10b-4c41-b075-89ce21ecf3b8' User entered 'None (0)'	System	02 Sep 2020 02:46:40
	System	02 Sep 2020 02:46:40

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:26', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '570863f1-b10b-4c41-b075-89ce21ecf3b8' User entered 'None (0)'	System	02 Sep 2020 02:46:40
	System	02 Sep 2020 02:46:40

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:29', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '570863f1-b10b-4c41-b075-89ce21ecf3b8' User entered 'None (0)'	System	02 Sep 2020 02:46:40
	System	02 Sep 2020 02:46:40

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:31', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '570863f1-b10b-4c41-b075-89ce21ecf3b8' User entered 'None (0)'	System	02 Sep 2020 02:46:40
	System	02 Sep 2020 02:46:40

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:34', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '570863f1-b10b-4c41-b075-89ce21ecf3b8' User entered 'No (N)'	System	02 Sep 2020 02:46:40
	System	02 Sep 2020 02:46:40

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-01T21:46:38', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '570863f1-b10b-4c41-b075-89ce21ecf3b8' User entered '01 Sep 2020 21:46'	System	02 Sep 2020 02:46:40
	System	02 Sep 2020 02:46:40

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 6'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:18', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ae59b4da-aa22-4c44-bf5d-e47e9835e5e1' User entered 'None (0)'	System	03 Sep 2020 01:39:36
	System	03 Sep 2020 01:39:36

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:20', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ae59b4da-aa22-4c44-bf5d-e47e9835e5e1' User entered 'None (0)'	System	03 Sep 2020 01:39:36
	System	03 Sep 2020 01:39:36

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:22', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ae59b4da-aa22-4c44-bf5d-e47e9835e5e1' User entered 'None (0)'	System	03 Sep 2020 01:39:36
	System	03 Sep 2020 01:39:36

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ae59b4da-aa22-4c44-bf5d-e47e9835e5e1' User entered 'None (0)'	System	03 Sep 2020 01:39:36
	System	03 Sep 2020 01:39:36

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:27', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ae59b4da-aa22-4c44-bf5d-e47e9835e5e1' User entered 'None (0)'	System	03 Sep 2020 01:39:36
	System	03 Sep 2020 01:39:36

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:29', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ae59b4da-aa22-4c44-bf5d-e47e9835e5e1' User entered 'None (0)'	System	03 Sep 2020 01:39:36
	System	03 Sep 2020 01:39:36

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:31', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ae59b4da-aa22-4c44-bf5d-e47e9835e5e1' User entered 'No (N)'	System	03 Sep 2020 01:39:36
	System	03 Sep 2020 01:39:36

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-02T20:39:34', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ae59b4da-aa22-4c44-bf5d-e47e9835e5e1' User entered '02 Sep 2020 20:39'	System	03 Sep 2020 01:39:36
	System	03 Sep 2020 01:39:36

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	28 Aug 2020 21:54:59
User entered 'Day 7'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:17', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '74124cb1-2734-42f7-a8c0-01338fb141a2' User entered 'None (0)'	System	04 Sep 2020 02:30:39
	System	04 Sep 2020 02:30:39

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '74124cb1-2734-42f7-a8c0-01338fb141a2' User entered 'None (0)'	System	04 Sep 2020 02:30:39
	System	04 Sep 2020 02:30:39

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:22', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '74124cb1-2734-42f7-a8c0-01338fb141a2' User entered 'None (0)'	System	04 Sep 2020 02:30:39
	System	04 Sep 2020 02:30:39

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '74124cb1-2734-42f7-a8c0-01338fb141a2' User entered 'None (0)'	System	04 Sep 2020 02:30:39
	System	04 Sep 2020 02:30:39

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:27', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '74124cb1-2734-42f7-a8c0-01338fb141a2' User entered 'None (0)'	System	04 Sep 2020 02:30:39
	System	04 Sep 2020 02:30:39

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:29', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '74124cb1-2734-42f7-a8c0-01338fb141a2' User entered 'None (0)'	System	04 Sep 2020 02:30:39
	System	04 Sep 2020 02:30:39

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:31', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '74124cb1-2734-42f7-a8c0-01338fb141a2'	System	04 Sep 2020 02:30:39
User entered 'No (N)'	System	04 Sep 2020 02:30:39

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-03T21:30:34', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '74124cb1-2734-42f7-a8c0-01338fb141a2'	System	04 Sep 2020 02:30:39
User entered '03 Sep 2020 21:30'	System	04 Sep 2020 02:30:39

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:54:59

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	03 Sep 2020 01:39:18
User entered 'Day 8'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:03:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-04T17:39:53', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a5ae44d2-d7d8-482c-b977-546e56c03d35'	System	04 Sep 2020 22:40:02
User entered 'None (1)'	System	04 Sep 2020 22:40:02

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:03:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-04T17:39:57', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a5ae44d2-d7d8-482c-b977-546e56c03d35'	System	04 Sep 2020 22:40:02
User entered '04 Sep 2020 17:39'	System	04 Sep 2020 22:40:02

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	03 Sep 2020 01:39:18
User entered 'Day 8'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-04T17:40:05', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'cedaaf7e-a23f-48a9-9d17-6805546351d5'	System	04 Sep 2020 22:40:12
User entered 'No (N)'	System	04 Sep 2020 22:40:12

US3062019

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-04T17:40:09', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'cedaaf7e-a23f-48a9-9d17-6805546351d5' User entered '04 Sep 2020 17:40'	System	04 Sep 2020 22:40:12
	System	04 Sep 2020 22:40:12

US3062019

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	03 Sep 2020 01:39:18
User entered 'Day 8'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:29

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)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-04T17:40:15', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '97a02275-1bcf-4638-b838-6e484b25d3da' User entered 'No (N)'	System	04 Sep 2020 22:40:23
	System	04 Sep 2020 22:40:23

US3062019

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-04T17:40:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '97a02275-1bcf-4638-b838-6e484b25d3da' User entered '04 Sep 2020 17:40'	System	04 Sep 2020 22:40:23
	System	04 Sep 2020 22:40:23

US3062019

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:39:18

US3062019

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:39:18

US3062019

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	04 Sep 2020 20:51:57
	(b) (4)	

US3062019

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '4 Sep 2020'	Colton King (b) (4)	04 Sep 2020 20:51:57
	(b) (4)	

US3062019

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	04 Sep 2020 20:51:57
	(b) (4)	

US3062019

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	Colton King (b) (4)	04 Sep 2020 20:51:57
	(b) (4)	

US3062019

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	04 Sep 2020 20:52:01
	(b) (4)	

US3062019

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'I'	System	04 Sep 2020 20:52:01

US3062019

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 20:31:00
	(b) (4)	

US3062019

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '11 Sep 2020'	Colton King (b) (4)	22 Sep 2020 20:31:00
	(b) (4)	

US3062019

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	22 Sep 2020 20:31:00
	(b) (4)	

US3062019

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	Colton King (b) (4)	22 Sep 2020 20:31:00
	(b) (4)	

US3062019

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 20:31:10
	(b) (4)	

US3062019

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'I'	System	22 Sep 2020 20:31:10

US3062019

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 20:31:29
	(b) (4)	

US3062019

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '18 Sep 2020'	Colton King (b) (4)	22 Sep 2020 20:31:29
	(b) (4)	

US3062019

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	22 Sep 2020 20:31:29
	(b) (4)	

US3062019

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered empty.	Colton King (b) (4)	22 Sep 2020 20:31:29
	(b) (4)	

US3062019

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 20:31:33
	(b) (4)	

US3062019

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'I'	System	22 Sep 2020 20:31:33

US3062019

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 20:32:03
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered '22 Sep 2020'	Colton King (b) (4)	22 Sep 2020 20:32:03
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
User entered 'Clinic (Clinic)'	(b) (4) Colton King (b) (4) (b) (4)	22 Sep 2020 20:32:03

US3062019

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'VISIT3'	System	22 Sep 2020 20:32:03

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 20:33:13
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered '22 Sep 2020'	Colton King (b) (4)	22 Sep 2020 20:33:13
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered '13:18'	Colton King (b) (4)	22 Sep 2020 20:33:13
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered '22 Sep 2020 13:18'	System	22 Sep 2020 20:33:13

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered '98.3' F	Colton King (b) (4)	22 Sep 2020 20:33:13
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	22 Sep 2020 20:33:13
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
User entered empty.	(b) (4) Colton King (b) (4) (b) (4)	22 Sep 2020 20:33:13

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered '84'	Colton King (b) (4)	22 Sep 2020 20:33:13
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'bpm'	System	22 Sep 2020 20:33:13

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered '16'	Colton King (b) (4)	22 Sep 2020 20:33:13
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'breaths/min'	System	22 Sep 2020 20:33:13

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered '97'	Colton King (b) (4)	22 Sep 2020 20:33:13
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'mmHg'	System	22 Sep 2020 20:33:13

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered '62'	Colton King (b) (4)	22 Sep 2020 20:33:13
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'mmHg'	System	22 Sep 2020 20:33:13

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Mar 2021 00:24:00

US3062019

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00

US3062019

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	22 Sep 2020 20:33:20
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:14:03
	(b) (4)	
User entered empty.	Colton King (b) (4)	22 Sep 2020 20:33:20
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 20:33:30
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered '22 Sep 2020'	(b) (4) Colton King (b) (4) (b) (4)	22 Sep 2020 20:33:30

US3062019

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
	(b) (4)	
User entered '13:38'	Colton King (b) (4)	22 Sep 2020 20:33:30
	(b) (4)	

US3062019

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered '22 Sep 2020 13:38'	System	22 Sep 2020 20:33:30

US3062019

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:45:35
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' answered with 'Updated per source. ' (Site from DM).	Cayla Lawless (b) (4)	10 Mar 2021 20:53:11
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4)	09 Mar 2021 11:09:29
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:13:53
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	22 Sep 2020 20:34:15

US3062019

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:24:00
User entered 'I'	System	22 Sep 2020 20:34:15

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 64'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-30T12:25:49', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e644ee4d-e69f-45b3-8bcc-766efcaf55ec'	System	30 Sep 2020 17:26:08
User entered 'No (N)'	System	30 Sep 2020 17:26:08

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-30T12:25:57', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e644ee4d-e69f-45b3-8bcc-766efcaf55ec'	System	30 Sep 2020 17:26:08
User entered 'No (N)'	System	30 Sep 2020 17:26:08

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-09-30T12:26:06', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e644ee4d-e69f-45b3-8bcc-766efcaf55ec' User entered '30 Sep 2020 12:26:06'	System	30 Sep 2020 17:26:08
	System	30 Sep 2020 17:26:08

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 71'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-10-08T16:32:27', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'cd51d8d3-773c-49bc-ad4e-5f3ee1d958c3' User entered 'No (N)'	System	08 Oct 2020 21:32:41
	System	08 Oct 2020 21:32:41

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-10-08T16:32:34', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'cd51d8d3-773c-49bc-ad4e-5f3ee1d958c3'	System	08 Oct 2020 21:32:41
User entered 'No (N)'	System	08 Oct 2020 21:32:41

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-10-08T16:32:40', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'cd51d8d3-773c-49bc-ad4e-5f3ee1d958c3' User entered '08 Oct 2020 16:32:40'	System	08 Oct 2020 21:32:41
	System	08 Oct 2020 21:32:41

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 78'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-10-14T09:10:18', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3f18d0db-a859-4865-ac48-2e0c6904f764'	System	14 Oct 2020 14:10:33
User entered 'No (N)'	System	14 Oct 2020 14:10:33

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-10-14T09:10:25', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3f18d0db-a859-4865-ac48-2e0c6904f764'	System	14 Oct 2020 14:10:33
User entered 'No (N)'	System	14 Oct 2020 14:10:33

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-10-14T09:10:32', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3f18d0db-a859-4865-ac48-2e0c6904f764' User entered '14 Oct 2020 09:10:32'	System	14 Oct 2020 14:10:33
	System	14 Oct 2020 14:10:33

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 92'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-10-28T07:32:20', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '99eff2a9-cda2-4803-a8af-16584920854e'	System	28 Oct 2020 12:32:40
User entered 'No (N)'	System	28 Oct 2020 12:32:40

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-10-28T07:32:28', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '99eff2a9-cda2-4803-a8af-16584920854e'	System	28 Oct 2020 12:32:40
User entered 'No (N)'	System	28 Oct 2020 12:32:40

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-10-28T07:32:35', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '99eff2a9-cda2-4803-a8af-16584920854e' User entered '28 Oct 2020 07:32:35'	System	28 Oct 2020 12:32:40
	System	28 Oct 2020 12:32:40

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 99'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-04T08:21:06', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f59f9c97-8875-45bf-981a-6114016866ff' User entered 'No (N)'	System	04 Nov 2020 14:21:21
	System	04 Nov 2020 14:21:21

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-04T08:21:11', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f59f9c97-8875-45bf-981a-6114016866ff'	System	04 Nov 2020 14:21:21
User entered 'No (N)'	System	04 Nov 2020 14:21:21

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-04T08:21:17', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f59f9c97-8875-45bf-981a-6114016866ff' User entered '04 Nov 2020 08:21:17'	System	04 Nov 2020 14:21:21
	System	04 Nov 2020 14:21:21

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 106'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-11T08:39:18', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a45413e1-6181-4ac7-8042-ae1c4de0b180' User entered 'No (N)'	System	11 Nov 2020 14:39:41
	System	11 Nov 2020 14:39:41

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-11T08:39:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a45413e1-6181-4ac7-8042-ae1c4de0b180' User entered 'No (N)'	System	11 Nov 2020 14:39:41
	System	11 Nov 2020 14:39:41

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-11T08:39:27', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'a45413e1-6181-4ac7-8042-ae1c4de0b180' User entered '11 Nov 2020 08:39:27'	System	11 Nov 2020 14:39:41
	System	11 Nov 2020 14:39:41

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered 'Day 113'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-18T20:45:04', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '9a6132c2-307c-429c-a685-bbe3a91d74c4'	System	19 Nov 2020 02:45:17
User entered 'No (N)'	System	19 Nov 2020 02:45:17

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-18T20:45:09', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '9a6132c2-307c-429c-a685-bbe3a91d74c4' User entered 'No (N)'	System	19 Nov 2020 02:45:17
	System	19 Nov 2020 02:45:17

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-18T20:45:13', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '9a6132c2-307c-429c-a685-bbe3a91d74c4' User entered '18 Nov 2020 20:45:13'	System	19 Nov 2020 02:45:17
	System	19 Nov 2020 02:45:17

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 23:05:48

US3062019

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:45
Data entry locked.	System	31 Jul 2020 23:05:48
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 23:05:48

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-24T08:02:29', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f79bdf23-6e35-4581-a9be-23ad21516dbb' User entered 'No (N)'	System	24 Nov 2020 14:02:43

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-24T08:02:37', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f79bdf23-6e35-4581-a9be-23ad21516dbb'	System	24 Nov 2020 14:02:43
User entered 'No (N)'	System	24 Nov 2020 14:02:43

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-24T08:02:42', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f79bdf23-6e35-4581-a9be-23ad21516dbb' User entered '24 Nov 2020 08:02:42'	System	24 Nov 2020 14:02:43
	System	24 Nov 2020 14:02:43

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-29T17:49:22', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23d9aa30-7cdb-4e89-8013-51371b4db4bb' User entered 'No (N)'	System	29 Nov 2020 23:49:34

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-29T17:49:28', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23d9aa30-7cdb-4e89-8013-51371b4db4bb' User entered 'No (N)'	System	29 Nov 2020 23:49:34

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-11-29T17:49:32', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '23d9aa30-7cdb-4e89-8013-51371b4db4bb' User entered '29 Nov 2020 17:49:32'	System	29 Nov 2020 23:49:34
	System	29 Nov 2020 23:49:34

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-06T07:59:51', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'fe0b3823-5ac3-401f-9e6c-e009d66e12fa' User entered 'No (N)'	System	06 Dec 2020 14:00:03
	System	06 Dec 2020 14:00:03

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-06T07:59:56', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'fe0b3823-5ac3-401f-9e6c-e009d66e12fa' User entered 'No (N)'	System	06 Dec 2020 14:00:03

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-06T08:00:01', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'fe0b3823-5ac3-401f-9e6c-e009d66e12fa' User entered '06 Dec 2020 08:00:01'	System	06 Dec 2020 14:00:03
	System	06 Dec 2020 14:00:03

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-13T08:43:11', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '41dd1ce4-383a-435a-9e77-5835ccc509f1' User entered 'No (N)'	System	13 Dec 2020 14:43:21
	System	13 Dec 2020 14:43:21

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-13T08:43:16', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '41dd1ce4-383a-435a-9e77-5835ccc509f1' User entered 'No (N)'	System	13 Dec 2020 14:43:21

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-13T08:43:19', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '41dd1ce4-383a-435a-9e77-5835ccc509f1' User entered '13 Dec 2020 08:43:19'	System	13 Dec 2020 14:43:21
	System	13 Dec 2020 14:43:21

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-20T00:03:27', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '96d44406-9d63-41bb-925f-be30e32e2a72' User entered 'No (N)'	System	20 Dec 2020 06:04:30
	System	20 Dec 2020 06:04:30

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-20T00:03:32', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '96d44406-9d63-41bb-925f-be30e32e2a72' User entered 'No (N)'	System	20 Dec 2020 06:04:30
	System	20 Dec 2020 06:04:30

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-20T00:04:27', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '96d44406-9d63-41bb-925f-be30e32e2a72' User entered '20 Dec 2020 00:04:27'	System	20 Dec 2020 06:04:30
	System	20 Dec 2020 06:04:30

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-27T08:42:44', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e475f4cb-e0fd-48e9-8346-8d314e300802' User entered 'No (N)'	System	27 Dec 2020 14:43:03
	System	27 Dec 2020 14:43:03

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-27T08:42:52', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e475f4cb-e0fd-48e9-8346-8d314e300802' User entered 'No (N)'	System	27 Dec 2020 14:43:03
	System	27 Dec 2020 14:43:03

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2020-12-27T08:43:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'e475f4cb-e0fd-48e9-8346-8d314e300802' User entered '27 Dec 2020 08:43:00'	System	27 Dec 2020 14:43:03
	System	27 Dec 2020 14:43:03

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-03T11:52:20', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '97b47763-077a-49ea-98a1-b5560bd33615'	System	03 Jan 2021 17:52:33
User entered 'No (N)'	System	03 Jan 2021 17:52:33

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-03T11:52:25', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '97b47763-077a-49ea-98a1-b5560bd33615'	System	03 Jan 2021 17:52:33
User entered 'No (N)'	System	03 Jan 2021 17:52:33

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-03T11:52:30', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '97b47763-077a-49ea-98a1-b5560bd33615' User entered '03 Jan 2021 11:52:30'	System	03 Jan 2021 17:52:33
	System	03 Jan 2021 17:52:33

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-10T00:42:22', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f7d12642-ea6b-47c8-9788-97f99fa037dc'	System	10 Jan 2021 06:42:33
User entered 'No (N)'	System	10 Jan 2021 06:42:33

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-10T00:42:26', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f7d12642-ea6b-47c8-9788-97f99fa037dc'	System	10 Jan 2021 06:42:33
User entered 'No (N)'	System	10 Jan 2021 06:42:33

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-10T00:42:30', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'f7d12642-ea6b-47c8-9788-97f99fa037dc' User entered '10 Jan 2021 00:42:30'	System	10 Jan 2021 06:42:33
	System	10 Jan 2021 06:42:33

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-17T12:11:56', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '981e489c-3c20-4297-aa35-410f2cc91108'	System	17 Jan 2021 18:12:09
User entered 'No (N)'	System	17 Jan 2021 18:12:09

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-17T12:12:01', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '981e489c-3c20-4297-aa35-410f2cc91108'	System	17 Jan 2021 18:12:09
User entered 'No (N)'	System	17 Jan 2021 18:12:09

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-17T12:12:05', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '981e489c-3c20-4297-aa35-410f2cc91108' User entered '17 Jan 2021 12:12:05'	System	17 Jan 2021 18:12:09
	System	17 Jan 2021 18:12:09

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-24T12:17:39', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '87e698fe-a26f-417d-ac31-3d1e86e0635b' User entered 'No (N)'	System	24 Jan 2021 18:17:56
	System	24 Jan 2021 18:17:56

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-24T12:17:49', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '87e698fe-a26f-417d-ac31-3d1e86e0635b' User entered 'No (N)'	System	24 Jan 2021 18:17:56
	System	24 Jan 2021 18:17:56

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-24T12:17:52', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '87e698fe-a26f-417d-ac31-3d1e86e0635b' User entered '24 Jan 2021 12:17:52'	System	24 Jan 2021 18:17:56
	System	24 Jan 2021 18:17:56

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-31T12:57:51', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'c81a297d-3b4f-4eec-a56e-298ec418caf2'	System	31 Jan 2021 18:58:07
User entered 'No (N)'	System	31 Jan 2021 18:58:07

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-31T12:58:01', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'c81a297d-3b4f-4eec-a56e-298ec418caf2'	System	31 Jan 2021 18:58:07
User entered 'No (N)'	System	31 Jan 2021 18:58:07

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-01-31T12:58:05', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'c81a297d-3b4f-4eec-a56e-298ec418caf2' User entered '31 Jan 2021 12:58:05'	System	31 Jan 2021 18:58:07
	System	31 Jan 2021 18:58:07

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-07T09:49:43', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8ce1d090-32ac-4be9-8c60-3e2471290eda' User entered 'No (N)'	System	07 Feb 2021 15:49:53
	System	07 Feb 2021 15:49:53

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-07T09:49:46', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8ce1d090-32ac-4be9-8c60-3e2471290eda' User entered 'No (N)'	System	07 Feb 2021 15:49:53

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-07T09:49:49', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '8ce1d090-32ac-4be9-8c60-3e2471290eda' User entered '07 Feb 2021 09:49:49'	System	07 Feb 2021 15:49:53
	System	07 Feb 2021 15:49:53

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-14T00:02:11', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b5d5127f-aa3a-45d2-a7fa-f51ffb1f4ad6'	System	14 Feb 2021 06:02:32
User entered 'No (N)'	System	14 Feb 2021 06:02:32

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-14T00:02:18', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b5d5127f-aa3a-45d2-a7fa-f51ffb1f4ad6'	System	14 Feb 2021 06:02:32
User entered 'No (N)'	System	14 Feb 2021 06:02:32

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-14T00:02:24', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b5d5127f-aa3a-45d2-a7fa-f51ffb1f4ad6'	System	14 Feb 2021 06:02:32
User entered '14 Feb 2021 00:02:24'	System	14 Feb 2021 06:02:32

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-21T08:00:13', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '93c2fa48-d4db-4c20-a466-fed340138954' User entered 'No (N)'	System	21 Feb 2021 14:00:31
	System	21 Feb 2021 14:00:31

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-21T08:00:18', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '93c2fa48-d4db-4c20-a466-fed340138954' User entered 'No (N)'	System	21 Feb 2021 14:00:31

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-21T08:00:28', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '93c2fa48-d4db-4c20-a466-fed340138954' User entered '21 Feb 2021 08:00:28'	System	21 Feb 2021 14:00:31
	System	21 Feb 2021 14:00:31

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-28T08:43:53-06:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3b0e73e5-274d-4ba4-affe-e9cefb42694d'	System	28 Feb 2021 14:44:05
User entered 'No (N)'	System	28 Feb 2021 14:44:05

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-28T08:43:57-06:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3b0e73e5-274d-4ba4-affe-e9cefb42694d' User entered 'No (N)'	System	28 Feb 2021 14:44:05
	System	28 Feb 2021 14:44:05

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-28T08:44:03-06:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '3b0e73e5-274d-4ba4-affe-e9cefb42694d'	System	28 Feb 2021 14:44:05
User entered '28 Feb 2021 14:44:03'	System	28 Feb 2021 14:44:05

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-07T04:15:21-06:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '0e491c74-acb6-46ce-8901-e1109febad12'	System	07 Mar 2021 10:15:44
User entered 'No (N)'	System	07 Mar 2021 10:15:44

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-07T04:15:36-06:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '0e491c74-acb6-46ce-8901-e1109febad12'	System	07 Mar 2021 10:15:44
User entered 'No (N)'	System	07 Mar 2021 10:15:44

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-07T04:15:41-06:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '0e491c74-acb6-46ce-8901-e1109febad12' User entered '07 Mar 2021 04:15:41'	System	07 Mar 2021 10:15:44
	System	07 Mar 2021 10:15:44

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-14T11:46:55-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '1af05783-113e-4898-9af3-783d6b550974'	System	14 Mar 2021 16:47:12
User entered 'No (N)'	System	14 Mar 2021 16:47:12

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-14T11:46:59-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '1af05783-113e-4898-9af3-783d6b550974'	System	14 Mar 2021 16:47:12
User entered 'No (N)'	System	14 Mar 2021 16:47:12

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-14T11:47:11-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '1af05783-113e-4898-9af3-783d6b550974' User entered '14 Mar 2021 11:47:11'	System	14 Mar 2021 16:47:12
	System	14 Mar 2021 16:47:12

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-21T07:23:52-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ed35cb26-e24d-400f-a030-5fe4a334a0b2'	System	21 Mar 2021 12:24:05
User entered 'No (N)'	System	21 Mar 2021 12:24:05

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-21T07:23:58-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ed35cb26-e24d-400f-a030-5fe4a334a0b2'	System	21 Mar 2021 12:24:05
User entered 'No (N)'	System	21 Mar 2021 12:24:05

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-21T07:24:01-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ed35cb26-e24d-400f-a030-5fe4a334a0b2'	System	21 Mar 2021 12:24:05
User entered '21 Mar 2021 07:24:01'	System	21 Mar 2021 12:24:05

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-28T08:56:48-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '33b5988e-8a12-4895-937b-fa40e6cf5122'	System	28 Mar 2021 13:57:00
User entered 'No (N)'	System	28 Mar 2021 13:57:00

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-28T08:56:52-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '33b5988e-8a12-4895-937b-fa40e6cf5122'	System	28 Mar 2021 13:57:00
User entered 'No (N)'	System	28 Mar 2021 13:57:00

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-03-28T08:56:56-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '33b5988e-8a12-4895-937b-fa40e6cf5122'	System	28 Mar 2021 13:57:00
User entered '28 Mar 2021 08:56:56'	System	28 Mar 2021 13:57:00

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-04T07:30:54-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '52953731-4607-49d8-910b-0b5190a743ee' User entered 'No (N)'	System	04 Apr 2021 12:31:09
	System	04 Apr 2021 12:31:09

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-04T07:31:01-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '52953731-4607-49d8-910b-0b5190a743ee' User entered 'No (N)'	System	04 Apr 2021 12:31:09

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-04T07:31:04-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '52953731-4607-49d8-910b-0b5190a743ee' User entered '04 Apr 2021 07:31:04'	System	04 Apr 2021 12:31:09
	System	04 Apr 2021 12:31:09

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-11T08:32:34-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ffcd7271-bc2f-40bf-936a-a11a2e5d042e' User entered 'No (N)'	System	11 Apr 2021 13:32:48
	System	11 Apr 2021 13:32:48

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-11T08:32:38-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ffcd7271-bc2f-40bf-936a-a11a2e5d042e' User entered 'No (N)'	System	11 Apr 2021 13:32:48
	System	11 Apr 2021 13:32:48

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-11T08:32:44-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'ffcd7271-bc2f-40bf-936a-a11a2e5d042e'	System	11 Apr 2021 13:32:48
User entered '11 Apr 2021 08:32:44'	System	11 Apr 2021 13:32:48

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-18T08:38:57-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '1aec60e8-9cd5-45c4-aef5-d2c79b2c6f7e'	System	18 Apr 2021 13:39:07
User entered 'No (N)'	System	18 Apr 2021 13:39:07

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-18T08:39:02-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '1aec60e8-9cd5-45c4-aef5-d2c79b2c6f7e' User entered 'No (N)'	System	18 Apr 2021 13:39:07

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-18T08:39:06-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '1aec60e8-9cd5-45c4-aef5-d2c79b2c6f7e'	System	18 Apr 2021 13:39:07
User entered '18 Apr 2021 08:39:06'	System	18 Apr 2021 13:39:07

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-25T07:46:19-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b269b08a-1516-4084-be2a-837330056a1d'	System	25 Apr 2021 12:46:43
User entered 'No (N)'	System	25 Apr 2021 12:46:43

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-25T07:46:31-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b269b08a-1516-4084-be2a-837330056a1d'	System	25 Apr 2021 12:46:43
User entered 'No (N)'	System	25 Apr 2021 12:46:43

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-04-25T07:46:38-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: 'b269b08a-1516-4084-be2a-837330056a1d'	System	25 Apr 2021 12:46:43
User entered '25 Apr 2021 07:46:38'	System	25 Apr 2021 12:46:43

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-05-02T13:36:17-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '79b9ddb3-eab4-44e0-bc10-4f98ad8aba10'	System	02 May 2021 18:36:32
User entered 'No (N)'	System	02 May 2021 18:36:32

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Have you been exposed to someone with 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 (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-05-02T13:36:24-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '79b9ddb3-eab4-44e0-bc10-4f98ad8aba10'	System	02 May 2021 18:36:32
User entered 'No (N)'	System	02 May 2021 18:36:32

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-05-02T13:36:27-05:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '79b9ddb3-eab4-44e0-bc10-4f98ad8aba10'	System	02 May 2021 18:36:32
User entered '02 May 2021 13:36:27'	System	02 May 2021 18:36:32

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 11:12:46

US3062019

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:12:46
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 11:12:46

US3062019

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:03:29

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 22:43:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-28T08:44:11-06:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4f06fdbb-406e-4042-8369-49d64ff0e8fa'	System	28 Feb 2021 14:44:21
User entered 'No (N)'	System	28 Feb 2021 14:44:21

US3062019

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:03:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:43:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C41035B-B805-483D-827B-C164002B4E70)', Time: '2021-02-28T08:44:16-06:00', User OID: 'PatientReportedOutcome (US3062019)', ODM File OID: '4f06fdbb-406e-4042-8369-49d64ff0e8fa' User entered '28 Feb 2021 14:44:16'	System	28 Feb 2021 14:44:21
	System	28 Feb 2021 14:44:21

US3062019

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:07:17
User entered 'Yes (Y)'	(b) (4) Sherry Henning (b) (4) (b) (4)	23 Oct 2020 19:10:10

US3062019

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:07:17
User entered '21 Oct 2020'	(b) (4) Sherry Henning (b) (4) (b) (4)	23 Oct 2020 19:10:10

US3062019

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:07:17
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	23 Oct 2020 19:10:10
	(b) (4)	

US3062019

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:07:17
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:10:10
	(b) (4)	

US3062019

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:07:17
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	27 Nov 2020 15:46:09
	(b) (4)	

US3062019

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:23:51
User entered 'I'	System	27 Nov 2020 15:46:09

US3062019

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	27 Nov 2020 15:46:16

US3062019

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '27 Nov 2020'	Riley King (b) (4)	27 Nov 2020 15:46:16

US3062019

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Riley King (b) (4)	27 Nov 2020 15:46:16

US3062019

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered empty.	Riley King (b) (4)	27 Nov 2020 15:46:16
	(b) (4)	

US3062019

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	Riley King (b) (4)	27 Nov 2020 15:46:20

US3062019

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered 'I'	System	27 Nov 2020 15:46:20

US3062019

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	27 Dec 2020 20:01:13

US3062019

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '27 Dec 2020'	(b) (4) Riley King (b) (4) (b) (4)	27 Dec 2020 20:01:13

US3062019

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	27 Dec 2020 20:01:13
	(b) (4)	

US3062019

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	27 Dec 2020 20:01:13

US3062019

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	27 Dec 2020 20:01:17

US3062019

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered 'I'	System	27 Dec 2020 20:01:17

US3062019

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	02 Feb 2021 21:08:21

US3062019

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '22 Jan 2021'	Riley King (b) (4)	02 Feb 2021 21:08:21

US3062019

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Riley King (b) (4) (b) (4)	02 Feb 2021 21:08:21

US3062019

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered empty.	Riley King (b) (4)	02 Feb 2021 21:08:21
	(b) (4)	

US3062019

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	02 Feb 2021 21:08:27

US3062019

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered 'I'	System	02 Feb 2021 21:08:27

US3062019

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	Cayla Lawless (b) (4)	10 Mar 2021 20:53:36

US3062019

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '19 Feb 2021'	Cayla Lawless (b) (4)	10 Mar 2021 20:53:36

US3062019

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[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 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Clinic (Clinic)'	(b) (4) Cayla Lawless (b) (4) (b) (4)	10 Mar 2021 20:53:36

US3062019

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered 'VISIT4'	System	10 Mar 2021 20:53:36

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '19 Feb 2021'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '12:39'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered '19 Feb 2021 12:39'	System	01 Apr 2021 22:04:08

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '97.8' F	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Oral (Oral)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '78'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered 'bpm'	System	01 Apr 2021 22:04:08

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '16'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered 'breaths/min'	System	01 Apr 2021 22:04:08

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '130'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered 'mmHg'	System	01 Apr 2021 22:04:08

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '78'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 22:04:08
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered 'mmHg'	System	01 Apr 2021 22:04:08

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13

US3062019

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13

US3062019

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'No (N)'	Cayla Lawless (b) (4)	10 Mar 2021 20:53:43

US3062019

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	Cayla Lawless (b) (4)	10 Mar 2021 20:53:43

US3062019

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	(b) (4) Cayla Lawless (b) (4)	10 Mar 2021 20:53:57
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered '19 Feb 2021'	Cayla Lawless (b) (4)	10 Mar 2021 20:53:57
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '12:47'	(b) (4) Cayla Lawless (b) (4)	10 Mar 2021 20:53:57
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered '19 Feb 2021 12:47'	System	10 Mar 2021 20:53:57

US3062019

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	(b) (4) Cayla Lawless (b) (4)	10 Mar 2021 20:54:03
	(b) (4)	

US3062019

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:13
User entered 'I'	System	10 Mar 2021 20:54:03

US3062019

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:28:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	Colton King (b) (4)	26 Mar 2021 14:56:38

US3062019

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:28:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '24 Mar 2021'	Colton King (b) (4)	26 Mar 2021 14:56:38

US3062019

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:28:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	26 Mar 2021 14:56:38

US3062019

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:28:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	Colton King (b) (4)	26 Mar 2021 14:56:38

US3062019

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:28:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	Colton King (b) (4)	26 Mar 2021 14:56:28

US3062019

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:28:53
User entered 'I'	System	26 Mar 2021 14:56:28

US3062019

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:57:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 22:14:05

US3062019

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:57:16
	(b) (4)	
User entered '23 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 22:14:05

US3062019

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:57:16
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Apr 2021 22:14:05

US3062019

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:57:16
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 22:14:05

US3062019

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:57:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 22:14:30

US3062019

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 22:14:30

US3062019

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	25 Jan 2021 18:39:21
	(b) (4)	

US3062019

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered '19 Jan 2021' reason for change: Data Entry Error	Cayla Lawless (b) (4)	22 Feb 2021 18:24:22
	(b) (4)	
User entered '22 Jan 2021'	Colton King (b) (4)	25 Jan 2021 18:39:21
	(b) (4)	

US3062019

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[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 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Clinic (Clinic)'	(b) (4) Colton King (b) (4) (b) (4)	25 Jan 2021 18:39:21

US3062019

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 18:39:21

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered '19 Jan 2021' reason for change: Data Entry Error	Cayla Lawless (b) (4)	22 Feb 2021 18:23:05
	(b) (4)	
User entered '22 Jan 2021'	Colton King (b) (4)	25 Jan 2021 18:39:37
	(b) (4)	

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

[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 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:10:44

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	Colton King (b) (4)	25 Jan 2021 18:39:37

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 16:05:08
User entered empty. WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:10:44

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered '19 Jan 2021' reason for change: Data Entry Error	Cayla Lawless (b) (4)	22 Feb 2021 18:23:05
	(b) (4)	
User entered '22 Jan 2021'	Colton King (b) (4)	25 Jan 2021 18:39:37
	(b) (4)	

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Colton King (b) (4)	25 Jan 2021 18:39:37
	(b) (4)	

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Colton King (b) (4)	25 Jan 2021 18:39:37
	(b) (4)	

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Colton King (b) (4)	25 Jan 2021 18:39:37

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	25 Jan 2021 18:39:37
	(b) (4)	

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User entered empty.	System	25 Jan 2021 18:39:37

US3062019

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User entered empty.	System	25 Jan 2021 18:39:37

US3062019

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	Colton King (b) (4)	25 Jan 2021 18:40:01

US3062019

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 is reported under Visit OL-1 visit in EDC, however sample dated 19Jan2021 appears to be in PPD central lab. Please review the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:35:07
User closed query 'The Collection Date is prior to the System Participant Decision Visit Date. Please review and reconcile.' (Site from System).		22 Feb 2021 18:24:22
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 is reported under Visit OL-1 visit in EDC, however sample dated 19Jan2021 appears to be in PPD central lab. Please review the details under appropriate visit. Else clarify, thank you.' answered with 'Date changed per source information. ' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	22 Feb 2021 18:24:13
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	22 Feb 2021 18:24:03
User entered '19 Jan 2021' reason for change: Data Entry Error	Cayla Lawless (b) (4) (b) (4)	22 Feb 2021 18:24:03
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 is reported under Visit OL-1 visit in EDC, however sample dated 19Jan2021 appears to be in PPD central lab. Please review the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 21:22:12
User entered '22 Jan 2021'	Colton King (b) (4) (b) (4)	25 Jan 2021 18:40:01

US3062019

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered '15:20'	Colton King (b) (4)	25 Jan 2021 18:40:01
	(b) (4)	

US3062019

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User entered '19 Jan 2021 15:20'	System	22 Feb 2021 18:24:03
User entered '22 Jan 2021 15:20'	System	25 Jan 2021 18:40:01

US3062019

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Yes (Y)'	Colton King (b) (4)	25 Jan 2021 18:40:14

US3062019

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "email to resolve query has been sent"; however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing accession, tracking number and shipped date. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Troy Holdeman (b) (4)	03 Apr 2021 11:48:40 02 Apr 2021 20:12:37
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "email to resolve query has been sent"; however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing accession, tracking number and shipped date. Thank you.' answered with 'e-mail sent on 3/3/21. Site used unscheduled kit. req 1F602155685 ' (Site from DM). User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "email to resolve query has been sent"; however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing accession, tracking number and shipped date. Thank you.' (Site from DM).	marissa Mueller (b) (4) (b) (4) (b) (4), (b) (6)	23 Mar 2021 17:11:38 19 Mar 2021 07:10:29
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 19JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 07:44:13
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 19JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'email to resolve query has been sent ' (Site from DM).	Colton King (b) (4) (b) (4)	03 Mar 2021 19:09:59

US3062019

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 19JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:31:01
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:32:31
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	22 Feb 2021 18:23:05
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'Data updated per source information.' (Site from DM).	Cayla Lawless (b) (4)	22 Feb 2021 18:22:29
User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	22 Feb 2021 18:22:10
User entered '19 Jan 2021' reason for change: Data Entry Error	Cayla Lawless (b) (4)	22 Feb 2021 18:22:10
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:36:36
User entered '22 Jan 2021'	Colton King (b) (4)	25 Jan 2021 18:40:14

US3062019

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:29

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '15:11'	(b) (4) Colton King (b) (4) (b) (4)	25 Jan 2021 18:40:14

US3062019

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:26
User entered '19 Jan 2021 15:11'	System	22 Feb 2021 18:22:10
User entered '22 Jan 2021 15:11'	System	25 Jan 2021 18:40:14

US3062019

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:03:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:18:20
User entered 'Yes (Y)'	Sherry Henning (b) (4) (b) (4)	09 Aug 2020 15:42:51

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:19:47
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 19:39:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 19:39:49
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 19:38:59
User entered 'HYPERTENSION'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:19:49
User entered 'Yes (Y)'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:19:52
User entered 'No (N)'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:19:54
User entered 'No (N)'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:19:58
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	12 Sep 2020 15:56:48
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	28 Aug 2020 21:54:59
User entered '04 Aug 2020'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:03
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:38:58

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:30
User entered 'Yes (Y)'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:32
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:54:40
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:38:58

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:10
User entered 'No (N)'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:12
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:18
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:20
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:22
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:24
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:26
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:29
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:31
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:33
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:38
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:39
User entered 'Not Related (NOT RELATED)'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:42
User entered 'Not Related (NOT RELATED)'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:45
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:41:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:41:14
User entered 'None (NONE)' reason for change: Data Entry Error	Janna Martinez (b) (4)	28 Aug 2020 19:41:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:38:58
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:47
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Aug 2020 19:41:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Aug 2020 19:38:58
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:52
User entered '1' reason for change: Data Entry Error	Janna Martinez (b) (4)	28 Aug 2020 19:41:48
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:54
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:20:58
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:21:02
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:38:58
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Aug 2020 19:38:58

US3062019

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 19:38:58

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:21:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:07:27
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	25 Sep 2020 15:07:20
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
User closed query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #5. Please reconcile and update so there is no overlap. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:57:23
Query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #5. Please reconcile and update so there is no overlap. Otherwise, clarify.' answered with 'This is correct as entered. The cellulitis and abscess occurred at the same time.' (Site from DM).	Jeri King (b) (4)	26 Oct 2020 20:42:41
User opened query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #5. Please reconcile and update so there is no overlap. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 00:57:22
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:21:26
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis knee - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 20:08:39
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 20:08:39
Data point term sent to Coder	System	23 Sep 2020 16:57:28
User entered 'Cellulitis Left Knee'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:21:28
User entered 'Yes (Y)'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:21:55
User entered 'No (N)'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4)	23 Oct 2020 19:21:59
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:22:01
User entered '18 Sep 2020'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:22:04
User entered empty.	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:56:38
DataPoint activated with code reason code Data required.	Colton King (b) (4) (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:14:42
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	26 Oct 2020 20:46:30
User entered 'Yes (Y)'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:31:09
DataPoint Un-verified.	Riley King (b) (4)	10 Feb 2021 15:17:16
	(b) (4)	
User entered '11 Oct 2020' reason for change: New Information	Riley King (b) (4)	10 Feb 2021 15:17:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:14:53
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)	27 Oct 2020 13:29:12
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).	Jeri King (b) (4)	26 Oct 2020 20:50:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Oct 2020 20:46:51
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 Oct 2020 20:46:51
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Oct 2020 20:46:30
User entered '26 Sep 2020' reason for change: Data Entry Error	Jeri King (b) (4)	26 Oct 2020 20:46:30
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)	20 Oct 2020 20:43:58
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)	20 Oct 2020 19:58:57

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'to be updated upon receipt of new information' (Site from Safety).	marissa Mueller (b) (4)	19 Oct 2020 20:09:05
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)	19 Oct 2020 13:32:36
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)	12 Oct 2020 15:18:03
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 ongoing' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:08:01
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 15:09:43
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:44:10
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 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:02:07
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 19:46:30
User entered empty.	Colton King (b) (4)	23 Sep 2020 16:56:38
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

1877 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not Sherry Henning required.	(b) (4) (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:22:28
User entered empty.	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:56:38
DataPoint activated with code reason code Data required.	Colton King (b) (4) (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:22:31
User closed query 'PV Query: Please clarify reported severity. Per SAE form, the severity is reported as 'Grade 4'; however, per EDC, the severity is reported as 'Grade 2/Moderate'.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:44:12
Query 'PV Query: Please clarify reported severity. Per SAE form, the severity is reported as 'Grade 4'; however, per EDC, the severity is reported as 'Grade 2/Moderate'.' answered with 'data corrected' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:04:04
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Janna Martinez (b) (4)	02 Oct 2020 21:02:37
	(b) (4)	
User opened query 'PV Query: Please clarify reported severity. Per SAE form, the severity is reported as 'Grade 4'; however, per EDC, the severity is reported as 'Grade 2/Moderate'.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 19:50:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:22:53
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	24 Sep 2020 21:26:03
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	24 Sep 2020 21:18:01
User entered 'Yes (Y)' reason for change: New Information	marissa Mueller (b) (4)	24 Sep 2020 21:18:01
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:22:56
User entered '0'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:23:02
User entered '0'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:23:05
	(b) (4), (b) (6)	
User closed query 'Per CDM, re-query: Response 'updated' noted, however Hospital Discharge Date and Admitted to ICU? is still missing. Please update or clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 08:20:56
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)	12 Oct 2020 08:20:52
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'corrected' (Site from System).	Jeri King (b) (4)	09 Oct 2020 23:08:35
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	09 Oct 2020 23:08:15
Query 'Per CDM, re-query: Response 'updated' noted, however Hospital Discharge Date and Admitted to ICU? is still missing. Please update or clarify.' answered with 'to be updated upon receipt of new information' (Site from DM).	marissa Mueller (b) (4)	25 Sep 2020 14:56:19
	(b) (4)	
User opened query 'Per CDM, re-query: Response 'updated' noted, however Hospital Discharge Date and Admitted to ICU? is still missing. Please update or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:33:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 08:31:21

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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 'udpated' (Site from System).	marissa Mueller (b) (4)	24 Sep 2020 21:26:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	24 Sep 2020 21:26:03
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:26:03
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:26:49
Query 'please verify as 23Sep2020 as per Hosp Discharge Summary' canceled (Site from CRA).		23 Oct 2020 19:26:47
User opened query 'please verify as 23Sep2020 as per Hosp Discharge Summary' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:23:50
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 19:23:25
DataPoint Verified.		23 Oct 2020 19:23:08
User entered '22 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 21:26:03
	(b) (4)	
User entered empty.	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:03
User entered '26 Sep 2020' reason for change: Data Entry Error	Jeri King (b) (4)	09 Oct 2020 23:08:50
User closed query 'PV Query: Please provide the hospital discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:44:16
Query 'PV Query: Please provide the hospital discharge date, when available.' answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:03:02
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 19:47:02
User entered empty.	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:10
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:18:10
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' answered with 'Information added' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:09:00
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	09 Oct 2020 23:08:15
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 15:11:14
User entered empty.	Colton King (b) (4)	23 Sep 2020 16:56:38
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:13
User entered empty.	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:16
User entered '0'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:19
User entered '0'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:26
User entered '0'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:29
	(b) (4), (b) (6)	02 Oct 2020 07:22:03
User closed query 'Per CDM: Please note that per page 34 of CCGs V2.0 SAEs that start prior to the first study dose must have a relationship of 'Not Applicable'. In all other cases 'Related' or 'Not related' should be selected for a Relationship to investigational product and study procedure. Please update as appropriate.' (Site from DM).		
Query 'PV Query: Please clarify reported causality. Per SAE form, the relationship to study drug and study procedure is reported as 'Not Related'; however, per EDC, the relationship to study drug and study procedure is reported as Not Applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 19:47:57
User opened query 'PV Query: Please clarify reported causality. Per SAE form, the relationship to study drug and study procedure is reported as 'Not Related'; however, per EDC, the relationship to study drug and study procedure is reported as Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 19:46:14
Query 'Per CDM: Please note that per page 34 of CCGs V2.0 SAEs that start prior to the first study dose must have a relationship of 'Not Applicable'. In all other cases 'Related' or 'Not related' should be selected for a Relationship to investigational product and study procedure. Please update as appropriate.' answered with 'error corrected' (Site from DM).	Sherry Henning (b) (4)	30 Sep 2020 15:04:58
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry Henning (b) (4)	30 Sep 2020 15:04:41
	(b) (4)	
User opened query 'Per CDM: Please note that per page 34 of CCGs V2.0 SAEs that start prior to the first study dose must have a relationship of 'Not Applicable'. In all other cases 'Related' or 'Not related' should be selected for a Relationship to investigational product and study procedure. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:33:14
User entered 'Not Applicable (NOT APPLICABLE)'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

1894 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:33
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	30 Sep 2020 15:04:41
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data	Colton King (b) (4)	23 Sep 2020 16:53:08
required.	(b) (4)	
DataPoint inactivated with code reason code Data not	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
required.	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:37
	(b) (4), (b) (6)	
User closed query 'PV Query: Please clarify reported action taken. Per SAE form, the action taken regarding study drug is reported as 'Not Applicable'; however, per EDC, the action taken regarding study drug is reported as 'None'.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:44:19
	(b) (4), (b) (6)	
Query 'PV Query: Please clarify reported action taken. Per SAE form, the action taken regarding study drug is reported as 'Not Applicable'; however, per EDC, the action taken regarding study drug is reported as 'None'.' answered with 'data corrected' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:02:53
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Janna Martinez (b) (4)	02 Oct 2020 21:02:37
	(b) (4)	
User opened query 'PV Query: Please clarify reported action taken. Per SAE form, the action taken regarding study drug is reported as 'Not Applicable'; however, per EDC, the action taken regarding study drug is reported as 'None'.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 19:49:22
	(b) (4), (b) (6)	
User entered 'None (NONE)'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:47
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	24 Sep 2020 21:26:32
User entered '0' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 21:26:32
	(b) (4)	
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	24 Sep 2020 21:26:03
User entered '1'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:24:43
User entered '1' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 21:26:03
	(b) (4)	
User entered '0'	Colton King (b) (4)	23 Sep 2020 16:56:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
User closed query 'please verify as yes per hosp discharge summary-irrigation and debridement of L knee abscess' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:16:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:16:11
Query 'please verify as yes per hosp discharge summary-irrigation and debridement of L knee abscess' answered with 'procedure has been added' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 15:27:37
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 15:27:17
User opened query 'please verify as yes per hosp discharge summary-irrigation and debridement of L knee abscess' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:25:37
User entered '0'	Colton King (b) (4)	23 Sep 2020 16:56:38
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:26
DataPoint Un-verified.	Riley King (b) (4)	10 Feb 2021 15:16:44
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Riley King (b) (4)	10 Feb 2021 15:16:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:16:05
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 13:29:16
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).	Jeri King (b) (4)	26 Oct 2020 20:50:26
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Jeri King (b) (4)	26 Oct 2020 20:46:51
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:32:50
User closed query 'PV Query: Please clarify reported outcome. Per SAE form, the outcome is reported as Recovering, however, per EDC, the outcome is reported as Not recovered.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:18:18
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).		12 Oct 2020 15:18:17

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify reported outcome. Per SAE form, the outcome is reported as Recovering, however, per EDC, the outcome is reported as Not recovered.' answered with 'updated' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:09:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jeri King (b) (4)	09 Oct 2020 23:09:37
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 'This remains ongoing' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:09:17
User opened query 'PV Query: Please clarify reported outcome. Per SAE form, the outcome is reported as Recovering, however, per EDC, the outcome is reported as Not recovered.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 15:11:48
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 15:10:03
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)	05 Oct 2020 12:44:22
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 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:03:10
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 19:46:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Colton King (b) (4)	23 Sep 2020 16:56:38

PRODUCTION RELEASE (v12.003
EAB) (1725)

1902 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:29
DataPoint Un-verified.	Riley King (b) (4)	10 Feb 2021 15:16:44
User entered empty; reason for change New Information	Riley King (b) (4)	10 Feb 2021 15:16:44
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:13:29
DataPoint Un-verified.		04 Nov 2020 18:34:05
DataPoint Verified.		04 Nov 2020 17:15:50
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	26 Oct 2020 20:47:25
User entered 'continues on antibiotics' reason for change: Data Entry Error	Jeri King (b) (4)	26 Oct 2020 20:47:25
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	26 Oct 2020 20:46:51
User entered empty.	Colton King (b) (4)	23 Sep 2020 16:56:38
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:32
User closed query 'Per DM CLR: Narrative = FLUID KNEE CULTURE WAS CONDUCTED ON 9/22/2020 AND TISSUE KNEE CULTURE WAS DONE ON 9/24/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:41:14
User closed query 'Per DM CLR: Narrative = BLOOD CULTURE WAS CONDUCTED ON 9/22/2020 AND 9/24/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:40:54
User closed query 'Per DM CLR: Narrative = ECHOCARDIOGRAM PERFORMED ON 9/24/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		02 Mar 2021 12:40:44
User closed query 'Per DM CLR: Narrative = SUBJECT HAD AN X-RAY OF LEFT KNEE ON 9/22/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		02 Mar 2021 12:40:37
Query 'Per DM CLR: Narrative = FLUID KNEE CULTURE WAS CONDUCTED ON 9/22/2020 AND TISSUE KNEE CULTURE WAS DONE ON 9/24/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	01 Mar 2021 17:56:46
Query 'Per DM CLR: Narrative = BLOOD CULTURE WAS CONDUCTED ON 9/22/2020 AND 9/24/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	01 Mar 2021 17:56:38

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = ECHOCARDIOGRAM PERFORMED ON 9/24/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	01 Mar 2021 17:56:31
Query 'Per DM CLR: Narrative = SUBJECT HAD AN X-RAY OF LEFT KNEE ON 9/22/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	01 Mar 2021 17:56:26
User opened query 'Per DM CLR: Narrative = FLUID KNEE CULTURE WAS CONDUCTED ON 9/22/2020 AND TISSUE KNEE CULTURE WAS DONE ON 9/24/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 02:44:30
User opened query 'Per DM CLR: Narrative = BLOOD CULTURE WAS CONDUCTED ON 9/22/2020 AND 9/24/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		28 Feb 2021 02:44:09
User opened query 'Per DM CLR: Narrative = ECHOCARDIOGRAM PERFORMED ON 9/24/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		28 Feb 2021 02:44:00
User opened query 'Per DM CLR: Narrative = SUBJECT HAD AN X-RAY OF LEFT KNEE ON 9/22/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		28 Feb 2021 02:43:55
DataPoint Un-verified.		
	Riley King (b) (4) (b) (4)	10 Feb 2021 15:18:08

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS SEEN AT SITE ON 9/22/2020 FOR VISIT 3. DURING THE VISIT, SUBJECT REPORTED CELLULITIS LEFT KNEE WHICH STARTED ON 9/18/2020. SUBJECT WAS SEEN BY HER PERSONAL DOCTOR AND STARTED ON ANTIBIOTICS ON 9/21/2020. AFTER HER SITE VISIT, SUBJECT WENT TO THE EMERGENCY ROOM FOR CELLULITIS. SUBJECT WAS ADMITTED TO HER LOCAL HOSPITAL AND WAS LATER TRANSFERRED TO A LARGER HOSPITAL. SUBJECT REPORTS SHE IS BEING GIVEN IV ANTIBIOTICS AND A SURGERY IS PLANNED FOR TOMORROW. SUBJECT IS UNSURE OF WHICH ANTIBIOTIC SHE IS BEING GIVEN AND DOES NOT KNOW WHAT SURGERY WILL BE PERFORMED. RELEASE OF RECORDS MAILED TO SUBJECT UPDATE 109/2020 SUBJECT HAD AN X-RAY OF LEFT KNEE ON 9/22/2020 WHICH SHOWED SURGICAL CHANGES IN THE LEFT KNEE WITHOUT OSSEOUS ABNORMALITY. SUBJECT HAD CHEST X-RAYS ON 9/24/2020, 9/25/2020 AND 9/26/2020. ECHOCARDIOGRAM PERFORMED ON 9/24/2020. COVID TEST ON 9/26/2020 WAS NEGATIVE. UPDATE PROVIDED 10/26/2020. PER INVESTIGATOR, SUBJECT'S STATUS STABILIZED AT TIME OF DISCHARGE FROM THE HOSPITAL. AFTER DISCHARGE FROM THE HOSPITAL, SUBJECT NO LONGER MET THE CRITERIA FOR SAE. STATUS UPDATED TO RECOVERED WITH SEQUAE DUE TO SUBJECT CONTINUING TO RECEIVE ANTIBIOTICS TO TREAT CELLULITIS. DURING HOSPITALIZATION, SUBJECT HAD BLOOD CULTURES WHICH INDICATED NO GROWTH AFTER 5 DAYS. ALSO, HAD CULTURE OF KNEE WHICH SHOWED "NO GROWTH". BLOOD CULTURE WAS CONDUCTED ON 9/22/2020 AND 9/24/2020. FLUID KNEE CULTURE WAS CONDUCTED ON	Riley King (b) (4) (b) (4)	10 Feb 2021 15:18:08

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
9/22/2020 AND TISSUE KNEE CULTURE WAS DONE ON 9/24/2020. Update on 02/10/2021 Updated end dates for con meds related to SAE. Also updated SAE from recovered with sequalae to recovered/resolved. Norco stop date was 10/11/2020 and Tylenol end date was 10/11/2020.' reason for change: New Information DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:16:01
User closed query 'Per DM CLR: Please review Other Action Taken and please note that there is a recorded therapeutic procedure that match this AE. However, ConProc is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).		03 Nov 2020 21:00:04
User closed query 'Per DM CLR: SAE Narrative indicates that the subject had Chest X Ray on 24th, 25th and 26th of September 2020 and an Echocardiogram on the 24th of September 2020. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).		03 Nov 2020 20:59:19
User closed query 'PV Query: Please provide the dates of the blood culture and knee culture.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 17:35:36
User closed query 'PV Query: Please clarify the type of knee culture performed (e.g. tissue, fluid etc.)' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 17:35:26
Query 'PV Query: Please clarify the type of knee culture performed (e.g. tissue, fluid etc.)' answered with 'Updated' (Site from Safety).	Justin Phillips (b) (4)	02 Nov 2020 21:23:28
Query 'PV Query: Please provide the dates of the blood culture and knee culture.' answered with 'Updated' (Site from Safety).	Justin Phillips (b) (4)	02 Nov 2020 21:23:20

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS SEEN AT SITE ON 9/22/2020 FOR VISIT 3. DURING THE VISIT, SUBJECT REPORTED CELLULITIS LEFT KNEE WHICH STARTED ON 9/18/2020. SUBJECT WAS SEEN BY HER PERSONAL DOCTOR AND STARTED ON ANTIBIOTICS ON 9/21/2020. AFTER HER SITE VISIT, SUBJECT WENT TO THE EMERGENCY ROOM FOR CELLULITIS. SUBJECT WAS ADMITTED TO HER LOCAL HOSPITAL AND WAS LATER TRANSFERRED TO A LARGER HOSPITAL. SUBJECT REPORTS SHE IS BEING GIVEN IV ANTIBIOTICS AND A SURGERY IS PLANNED FOR TOMORROW. SUBJECT IS UNSURE OF WHICH ANTIBIOTIC SHE IS BEING GIVEN AND DOES NOT KNOW WHAT SURGERY WILL BE PERFORMED. RELEASE OF RECORDS MAILED TO SUBJECT UPDATE 109/2020 SUBJECT HAD AN X-RAY OF LEFT KNEE ON 9/22/2020 WHICH SHOWED SURGICAL CHANGES IN THE LEFT KNEE WITHOUT OSSEOUS ABNORMALITY. SUBJECT HAD CHEST X-RAYS ON 9/24/2020, 9/25/2020 AND 9/26/2020. ECHOCARDIOGRAM PERFORMED ON 9/24/2020. COVID TEST ON 9/26/2020 WAS NEGATIVE. UPDATE PROVIDED 10/26/2020. PER INVESTIGATOR, SUBJECT'S STATUS STABILIZED AT TIME OF DISCHARGE FROM THE HOSPITAL. AFTER DISCHARGE FROM THE HOSPITAL, SUBJECT NO LONGER MET THE CRITERIA FOR SAE. STATUS UPDATED TO RECOVERED WITH SEQUAE DUE TO SUBJECT CONTINUING TO RECEIVE ANTIBIOTICS TO TREAT CELLULITIS. DURING HOSPITALIZATION, SUBJECT HAD BLOOD CULTURES WHICH INDICATED NO GROWTH AFTER 5 DAYS. ALSO, HAD CULTURE OF KNEE WHICH SHOWED "NO GROWTH". Blood culture was conducted on 9/22/2020 and 9/24/2020. Fluid knee culture was conducted on 9/22/2020 and tissue knee culture was	Justin Phillips (b) (4)	02 Nov 2020 21:22:51

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
done on 9/24/2020.' reason for change: Data Entry Error		
User opened query 'PV Query: Please clarify the type of knee culture performed (e.g. tissue, fluid etc.)' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:15:19
User opened query 'PV Query: Please provide the dates of the blood culture and knee culture.' (Site from Safety).		30 Oct 2020 21:15:14
User closed query 'PV Query: Please provide the results of any cultures performed (i.e. blood, wound). If not provided, please state so.' (Site from Safety).		27 Oct 2020 13:29:18
Query 'Per DM CLR: SAE Narrative indicates that the subject had Chest X Ray on 24th, 25th and 26th of September 2020 and an Echocardiogram on the 24th of September 2020. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jeri King (b) (4)	26 Oct 2020 20:52:56
Query 'Per DM CLR: Please review Other Action Taken and please note that there is a recorded therapeutic procedure that match this AE. However, ConProc is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jeri King (b) (4)	26 Oct 2020 20:50:52
Query 'PV Query: Please provide the results of any cultures performed (i.e. blood, wound). If not provided, please state so.' answered with 'information added' (Site from Safety).	Jeri King (b) (4)	26 Oct 2020 20:50:34
DataPoint Un-verified.	Jeri King (b) (4)	26 Oct 2020 20:49:36

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS SEEN AT SITE ON 9/22/2020 FOR VISIT 3. DURING THE VISIT, SUBJECT REPORTED CELLULITIS LEFT KNEE WHICH STARTED ON 9/18/2020. SUBJECT WAS SEEN BY HER PERSONAL DOCTOR AND STARTED ON ANTIBIOTICS ON 9/21/2020. AFTER HER SITE VISIT, SUBJECT WENT TO THE EMERGENCY ROOM FOR CELLULITIS. SUBJECT WAS ADMITTED TO HER LOCAL HOSPITAL AND WAS LATER TRANSFERRED TO A LARGER HOSPITAL. SUBJECT REPORTS SHE IS BEING GIVEN IV ANTIBIOTICS AND A SURGERY IS PLANNED FOR TOMORROW. SUBJECT IS UNSURE OF WHICH ANTIBIOTIC SHE IS BEING GIVEN AND DOES NOT KNOW WHAT SURGERY WILL BE PERFORMED. RELEASE OF RECORDS MAILED TO SUBJECT UPDATE 109/2020 SUBJECT HAD AN X-RAY OF LEFT KNEE ON 9/22/2020 WHICH SHOWED SURGICAL CHANGES IN THE LEFT KNEE WITHOUT OSSEOUS ABNORMALITY. SUBJECT HAD CHEST X-RAYS ON 9/24/2020, 9/25/2020 AND 9/26/2020. ECHOCARDIOGRAM PERFORMED ON 9/24/2020. COVID TEST ON 9/26/2020 WAS NEGATIVE. Update provided 10/26/2020. Per investigator, subject's status stabilized at time of discharge from the hospital. After discharge from the hospital, subject no longer met the criteria for SAE. Status updated to recovered with sequelae due to subject continuing to receive antibiotics to treat cellulitis. During hospitalization, subject had blood cultures which indicated no growth after 5 days. Also, had culture of knee which showed "no growth".' reason for change: Data Entry Error	Jeri King (b) (4)	26 Oct 2020 20:49:36
User opened query 'Per DM CLR: Please review Other Action Taken and please note that there is a recorded therapeutic procedure that match this AE. However, ConProc is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 00:57:04

PRODUCTION RELEASE (v12.003
EAB) (1725)

1911 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative indicates that the subject had Chest X Ray on 24th, 25th and 26th of September 2020 and an Echocardiogram on the 24th of September 2020. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	25 Oct 2020 00:56:56
		23 Oct 2020 19:26:57
User closed query 'PV Query: Please confirm if additional diagnosis of sepsis was made with lactic acid of 21.3.' (Site from Safety).		21 Oct 2020 15:24:44
Query 'PV Query: Please confirm if additional diagnosis of sepsis was made with lactic acid of 21.3. answered with 'Diagnosis of sepsis was not listed in medical records. ' (Site from Safety).	Jeri King (b) (4)	20 Oct 2020 21:00:08
User opened query 'PV Query: Please confirm if additional diagnosis of sepsis was made with lactic acid of 21.3.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:33:37
User opened query 'PV Query: Please provide the results of any cultures performed (i.e. blood, wound). If not provided, please state so.' (Site from Safety).		19 Oct 2020 13:33:21
User closed query 'PV Query: The subject was scheduled for an unknown surgery. Please clarify indication for the procedure and if there were any complications associate with knee cellulitis.' (Site from Safety).		12 Oct 2020 15:18:38
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).		12 Oct 2020 15:18:36
User closed query 'PV Query: Please report the underlying etiology/source of the left knee cellulitis.' (Site from Safety).		12 Oct 2020 15:18:35
User closed query 'PV Query: Per the SAE form, total knee replacement, OA bilateral knees, and edema bilateral lower extremities were reported as relevant medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).		12 Oct 2020 15:18:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

1912 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' ' (Site from Safety).</td <td rowspan="3">(b) (4), (b) (6)</td> <td>12 Oct 2020 15:18:31</td>	(b) (4), (b) (6)	12 Oct 2020 15:18:31
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cultures. Please include units and reference ranges if applicable.' (Site from Safety).</td <td>12 Oct 2020 15:18:30</td>		12 Oct 2020 15:18:30
User closed query 'Per DM CLR: SAE Narrative = Patient was given IV antibiotics and a possible surgery will be performed. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		12 Oct 2020 08:25:24

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS SEEN AT SITE ON 9/22/2020 FOR VISIT 3. DURING THE VISIT, SUBJECT REPORTED CELLULITIS LEFT KNEE WHICH STARTED ON 9/18/2020. SUBJECT WAS SEEN BY HER PERSONAL DOCTOR AND STARTED ON ANTIBIOTICS ON 9/21/2020. AFTER HER SITE VISIT, SUBJECT WENT TO THE EMERGENCY ROOM FOR CELLULITIS. SUBJECT WAS ADMITTED TO HER LOCAL HOSPITAL AND WAS LATER TRANSFERRED TO A LARGER HOSPITAL. SUBJECT REPORTS SHE IS BEING GIVEN IV ANTIBIOTICS AND A SURGERY IS PLANNED FOR TOMORROW. SUBJECT IS UNSURE OF WHICH ANTIBIOTIC SHE IS BEING GIVEN AND DOES NOT KNOW WHAT SURGERY WILL BE PERFORMED. RELEASE OF RECORDS MAILED TO SUBJECT UPDATE 109/2020 Subject had an X-ray of left knee on 9/22/2020 which showed surgical changes in the left knee without osseous abnormality. Subject had chest X-rays on 9/24/2020, 9/25/2020 and 9/26/2020. Echocardiogram performed on 9/24/2020. COVID test on 9/26/2020 was negative.' reason for change: Data Entry Error	Jeri King (b) (4)	09 Oct 2020 23:17:13
Query 'PV Query: Per the SAE form, total knee replacement, OA bilateral knees, and edema bilateral lower extremities were reported as relevant medical history (prior to start of study). If considered MH, please add to MH eCRF.' answered with 'updated' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:15:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cultures. Please include units and reference ranges if applicable.' answered with 'SAE form updated' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:11:27
Query 'PV Query: The subject was scheduled for an unknown surgery. Please clarify indication for the procedure and if there were any complications associate with knee cellulitis.' answered with 'Waiting for procedure report. Requested again 10/9/2020' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:11:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

1914 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
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 'see narrative' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:10:58
Query 'PV Query: Please report the underlying etiology/source of the left knee cellulitis.' answered with 'Infection is the underlying etiology' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:10:51
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'conmed page updated' (Site from Safety).	Jeri King (b) (4)	09 Oct 2020 23:10:34
User opened query 'PV Query: The subject was scheduled for an unknown surgery. Please clarify indication for the procedure and if there were any complications associate with knee cellulitis.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 15:12:51
Query 'Safety Medical Query: The subject was scheduled for an unknown surgery. Please clarify indication for the procedure and if there were any complications associate with knee cellulitis.' canceled (Site from Safety).		09 Oct 2020 15:12:33
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).		09 Oct 2020 15:12:12
User opened query 'Safety Medical Query: The subject was scheduled for an unknown surgery. Please clarify indication for the procedure and if there were any complications associate with knee cellulitis.' (Site from Safety).		09 Oct 2020 15:11:59
User opened query 'PV Query: Please report the underlying etiology/source of the left knee cellulitis.' (Site from Safety).		09 Oct 2020 15:11:29

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per the SAE form, total knee replacement, OA bilateral knees, and edema bilateral lower extremities were reported as relevant medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 15:10:45
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).		09 Oct 2020 15:10:29
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cultures. Please include units and reference ranges if applicable.' (Site from Safety).		09 Oct 2020 15:10:19
User closed query 'PV Query: Please report the underlying etiology/source of the left knee cellulitis.' (Site from Safety).		05 Oct 2020 12:44:35
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).		05 Oct 2020 12:44:31
User closed query 'PV Query: Per the SAE form, total knee replacement, OA bilateral knees, and edema bilateral lower extremities were reported as relevant medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).		05 Oct 2020 12:44:30
User closed query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:44:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cultures. Please include units and reference ranges if applicable.' (Site from Safety).		05 Oct 2020 12:44:26

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[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)	05 Oct 2020 12:44:24
Query 'Per DM CLR: SAE Narrative = Patient was given IV antibiotics and a possible surgery will be performed. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF.'	Janna Martinez (b) (4)	02 Oct 2020 21:03:55
' answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from DM).	(b) (4)	
Query 'PV Query: Please report the underlying etiology/source of the left knee cellulitis.' answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:03:50
	(b) (4)	
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.'	Janna Martinez (b) (4)	02 Oct 2020 21:03:44
answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	(b) (4)	
Query 'PV Query: Per the SAE form, total knee replacement, OA bilateral knees, and edema bilateral lower extremities were reported as relevant medical history (prior to start of study). If considered MH, please add to MH eCRF.' answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4)	02 Oct 2020 21:03:33
	(b) (4)	
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).'	Janna Martinez (b) (4)	02 Oct 2020 21:03:28
answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

1917 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cultures. Please include units and reference ranges if applicable.' answered with 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4) (b) (4)	02 Oct 2020 21:03:22
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 'medical records have been request but not yet received, will up date as soon as we receive the information.' (Site from Safety).	Janna Martinez (b) (4) (b) (4)	02 Oct 2020 21:03:17
User entered 'SUBJECT WAS SEEN AT SITE ON 9/22/2020 FOR VISIT 3. DURING THE VISIT, SUBJECT REPORTED CELLULITIS LEFT KNEE WHICH STARTED ON 9/18/2020. SUBJECT WAS SEEN BY HER PERSONAL DOCTOR AND STARTED ON ANTIBIOTICS ON 9/21/2020. AFTER HER SITE VISIT, SUBJECT WENT TO THE EMERGENCY ROOM FOR CELLULITIS. SUBJECT WAS ADMITTED TO HER LOCAL HOSPITAL AND WAS LATER TRANSFERRED TO A LARGER HOSPITAL. SUBJECT REPORTS SHE IS BEING GIVEN IV ANTIBIOTICS AND A SURGERY IS PLANNED FOR TOMORROW. SUBJECT IS UNSURE OF WHICH ANTIBIOTIC SHE IS BEING GIVEN AND DOES NOT KNOW WHAT SURGERY WILL BE PERFORMED. RELEASE OF RECORDS MAILED TO SUBJECT' reason for change: Data Entry Error	Janna Martinez (b) (4) (b) (4)	02 Oct 2020 20:56:12
User opened query 'Per DM CLR: SAE Narrative = Patient was given IV antibiotics and a possible surgery will be performed. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 23:56:26
User opened query 'PV Query: Please report the underlying etiology/source of the left knee cellulitis.' (Site from Safety).		01 Oct 2020 19:51:39

PRODUCTION RELEASE (v12.003
EAB) (1725)

1918 of 3177

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 19:50:32
User opened query 'PV Query: Per the SAE form, total knee replacement, OA bilateral knees, and edema bilateral lower extremities were reported as relevant medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).		01 Oct 2020 19:49:39
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).		01 Oct 2020 19:47:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cultures. Please include units and reference ranges if applicable.' (Site from Safety).		01 Oct 2020 19:47:16
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).		01 Oct 2020 19:45:07
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Sep 2020 21:26:03
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 21:26:03

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject was seen at site on 9/22/2020 for Visit 3. During the visit, subject reported cellulitis left knee which started on 9/18/2020. Subject was seen by her personal doctor and started on antibiotics on 9/21/2020. After her site visit, subject went to the Emergency Room for cewllulitis. Subject was admitted to her local hospital and was later transferred to a larger hospital. Subject reports she is being given IV antibiotics and a surgery is planned for tomorrow. Subject is unsure of which antibiotic she is being given and does not know what surgery will be performed. Release of records mailed to subject' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 21:26:03
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Sep 2020 21:18:01
User entered empty.	Colton King (b) (4)	23 Sep 2020 16:56:38
DataPoint activated with code reason code Data required.	Colton King (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 21:18:01
User entered '0'	System	23 Sep 2020 16:56:38
DataPoint activated with code reason code Data required.	Colton King (b) (4) (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 16:56:38
DataPoint activated with code reason code Data required.	Colton King (b) (4) (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 23:08:15
DataPoint activated with code reason code Data required.	Colton King (b) (4) (b) (4)	23 Sep 2020 16:53:08
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Sep 2020 00:20:41

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:27:36
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 18:56:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 18:56:22
Data point term sent to Coder	System	13 Oct 2020 18:55:52
User entered 'Dehydration'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:27:40
User entered 'Yes (Y)'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:27:42
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:27:44
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:28:16
User entered '22 Sep 2020'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:28:18
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Oct 2020 18:56:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 18:56:07
User entered empty; reason for change Data Entry Error	Jeri King (b) (4)	13 Oct 2020 18:56:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 18:55:37
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Oct 2020 18:55:37
User entered 'un:un' (non-conformant).	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User entered empty.	System	13 Oct 2020 18:56:07
User entered '22 Sep 2020 UN:UN' (non-conformant).	System	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:28:20
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:28:24
User entered '25 Sep 2020'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:28:27
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	13 Oct 2020 18:56:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 18:56:07
User entered empty; reason for change Data Entry Error	Jeri King (b) (4)	13 Oct 2020 18:56:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 18:55:37
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	13 Oct 2020 18:55:37
User entered 'Un:Un' (non-conformant).	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User entered empty.	System	13 Oct 2020 18:56:07
User entered '25 Sep 2020 UN:UN' (non-conformant).	System	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:28:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:28:30
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:28:41
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 19:28:44
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:28:46
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:28:50
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:28:52
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:28:58
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:29:01
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:29:03
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:29:05
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:29:08
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:29:11
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:56:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:56:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jeri King (b) (4)	13 Oct 2020 18:56:07
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:55:37
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:29:14
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:29:17
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:56:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:56:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jeri King (b) (4)	13 Oct 2020 18:56:07
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:55:37
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:29:22
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:29:42
User entered 'I'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:29:45
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:29:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:29:49
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:29:52
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User entered '0'	System	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54
User entered '1'	System	13 Oct 2020 18:55:37

US3062019

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:54

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
User closed query 'Per DM CLR: Please review if this AE is a downgrade of AE #3. If yes, please note that AE downgrades are not recorded as a new AE entry. The AE with the highest grade remains ongoing until its resolution. Please reconcile and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 21:00:39
Query 'Per DM CLR: Please review if this AE is a downgrade of AE #3. If yes, please note that AE downgrades are not recorded as a new AE entry. The AE with the highest grade remains ongoing until its resolution. Please reconcile and update applicable details accordingly. Otherwise, clarify.' answered with 'This is correct as entered. The cellulitis and abscess occurred at the same time. These were 2 separate AEs.	Jeri King (b) (4)	26 Oct 2020 20:43:15
' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 00:57:49
User opened query 'Per DM CLR: Please review if this AE is a downgrade of AE #3. If yes, please note that AE downgrades are not recorded as a new AE entry. The AE with the highest grade remains ongoing until its resolution. Please reconcile and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:30:23
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 05:53:59
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Joint abscess, LLT: Joint abscess - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 05:53:59
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	(b) (4)	13 Oct 2020 18:57:57
Data point term sent to Coder	System	13 Oct 2020 18:57:31
User entered 'Left Knee Abscess'	Jeri King (b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:30:25
User entered 'Yes (Y)'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:30:27
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:30:30
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:30:32
User entered '22 Sep 2020'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:30:38
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User entered empty.	System	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:47:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Un-verified.	(b) (4) Riley King (b) (4)	10 Feb 2021 15:19:28
User entered 'No (N)' reason for change: New Information	(b) (4) Riley King (b) (4)	10 Feb 2021 15:19:28
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.'	(b) (4), (b) (6)	18 Dec 2020 13:59:19
(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.'	marissa Mueller (b) (4)	15 Dec 2020 20:45:40
' answered with 'event is ongoing' (Site from DM).	(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.'	(b) (4), (b) (6)	25 Nov 2020 03:48:23
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:24:25
User entered 'Yes (Y)'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:47:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	10 Feb 2021 15:19:40
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Feb 2021 15:19:40
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 15:19:28
DataPoint Un-verified.	Riley King (b) (4)	10 Feb 2021 15:19:28
User entered '16 Oct 2020' reason for change: New Information	Riley King (b) (4)	10 Feb 2021 15:19:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:24:29
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:30:52
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User entered empty.	System	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:31:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:31:33
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:31:40
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:31:42
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:31:50
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:31:54
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:31:57
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:32:00
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:32:03
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:32:06
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:32:11
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:32:14
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:32:16
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:32:19
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:32:21
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:57:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:57:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jeri King (b) (4)	13 Oct 2020 18:57:41
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:57:31
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:32:23
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:32:35
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:32:39
User entered 'I'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:47:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Un-verified.	Riley King (b) (4)	10 Feb 2021 15:19:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Riley King (b) (4)	10 Feb 2021 15:19:40
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:24:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	04 Nov 2020 17:24:40
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:33:01
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User entered '0'	System	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55
User entered '1'	System	13 Oct 2020 18:57:31

US3062019

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:55

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:51
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:51
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:33:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 19:00:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 19:00:14
Data point term sent to Coder	System	13 Oct 2020 18:59:01
User entered 'Nausea'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:33:17
User entered 'Yes (Y)'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:33:20
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:33:22
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 19:33:24
User entered '24 Sep 2020'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:33:27
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User entered empty.	System	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:33:29
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:58:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:58:47
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	13 Oct 2020 18:58:47
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:58:38
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:33:33
User entered '24 Sep 2020'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:33:35
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User entered empty.	System	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:33:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:33:48
User entered 'No (N)'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:33:50
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:33:52
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:33:57
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:00
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:02
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:04
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:07
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:10
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:12
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:15
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:19
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:21
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:24
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:25
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:28
User entered 'I'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:33
User entered '0'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:34:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4)	23 Oct 2020 19:34:37
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:34:42
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User entered '0'	System	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User entered '1'	System	13 Oct 2020 18:58:38

US3062019

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
User closed query 'Per DM CLR: Please review this AE as it was noted as a recurrent event. However, there is no MH or prior AE that would support this recurrent condition. Please update to record the previous event as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 12:11:36
Query 'Per DM CLR: Please review this AE as it was noted as a recurrent event. However, there is no MH or prior AE that would support this recurrent condition. Please update to record the previous event as appropriate. Otherwise, clarify.' answered with 'correct as entered per records' (Site from DM).	marissa Mueller (b) (4)	20 Nov 2020 22:53:11
User opened query 'Per DM CLR: Please review this AE as it was noted as a recurrent event. However, there is no MH or prior AE that would support this recurrent condition. Please update to record the previous event as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:21:36
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\23.0.	(b) (4), (b) (6)	23 Oct 2020 19:35:04
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 23:35:38
Data point term sent to Coder	(b) (4)	
User entered 'heart murmur recurrent'	Coder Import (b) (4)	21 Oct 2020 23:35:38
	(b) (4)	
	System	21 Oct 2020 22:07:19
	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:08
User entered 'Yes (Y)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:10
User entered 'No (N)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:12
User entered 'No (N)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:15
User entered '23 Sep 2020'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:17
User entered empty.	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:06:53

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:25:25
User entered 'Yes (Y)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:25:29
User entered empty.	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:25:31
User entered empty.	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:06:53

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:29
User entered 'No (N)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:31
User entered '0'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:34
User entered '0'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:36
User entered '0'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:41
User entered empty.	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:43
User entered empty.	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:45
User entered empty.	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:47
User entered empty.	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:50
User entered '0'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:52
User entered '0'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:54
User entered '0'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:35:56
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:36:00
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:36:02
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:36:05
User entered 'I'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:36:07
User entered '0'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:36:10
User entered '0'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:25:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:25:37
User entered empty.	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:52:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:36:16
User entered empty.	marissa Mueller (b) (4)	21 Oct 2020 22:06:53
	(b) (4)	

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 22:06:53

US3062019

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 22:06:53

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:03:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:37:27
User entered 'Yes (Y)'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 20:46:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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)	01 Aug 2020 20:49:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 20:49:16
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:48:40
User entered 'vitamin C'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4), (b) (6)	
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).		16 Sep 2020 08:08:43
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	15 Sep 2020 00:27:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Sep 2020 00:27:05
	(b) (4)	
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 09:49:17
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'nutritional supplement'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '100'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4), (b) (6)	03 Aug 2020 13:42:28
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:48:35
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:48:19
User entered 'un Jan 2020'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:48:19
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:48:19

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:48:19

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:48:19

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:24
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)	01 Aug 2020 20:50:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 20:50:17
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:49:43
User entered 'multivitamin'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:27
	(b) (4), (b) (6)	
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 08:08:53
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'udpated' (Site from DM).	marissa Mueller (b) (4)	15 Sep 2020 00:27:15
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Sep 2020 00:27:12
	(b) (4)	
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:24:41
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:29
User entered 'nutritional supplement'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:31
User entered '2'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:34
User entered 'tablet (TABLET)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:36
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:38
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:43
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:45
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:47
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:47:50
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		03 Aug 2020 13:42:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:49:08
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:49:04
User entered 'un UNK 2015'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:49:15
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:49:31
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:49:34
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:49:35
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:49:04

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:49:04

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:49:04

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:49:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 20:50:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 20:50:16
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:49:43
User entered 'vitamin D3'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:49:49
	(b) (4), (b) (6)	
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).		16 Sep 2020 07:54:03
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	15 Sep 2020 00:27:25
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Sep 2020 00:27:21
	(b) (4)	
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:24:57
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User closed query 'Per CDM, per DM CLR re-query: Response noted; however, please review and verify the dose unit as per the DM CLR query. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:03:04
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:49:50
Query 'Per CDM, per DM CLR re-query: Response noted; however, please review and verify the dose unit as per the DM CLR query. Thank you. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	16 Oct 2020 16:58:16
	(b) (4)	
User opened query 'Per CDM, per DM CLR re-query: Response noted; however, please review and verify the dose unit as per the DM CLR query. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 07:59:04
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 07:59:04
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 per source' (Site from DM).	marissa Mueller (b) (4)	15 Sep 2020 00:27:41
	(b) (4)	
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)	10 Sep 2020 04:55:14
User entered 'nutritional supplement'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:49:59
User entered '2000' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Sep 2020 00:27:36
	(b) (4)	
User entered '200'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:04
User entered 'IU (IU)' reason for change: Data Entry Error	marissa Mueller (b) (4)	16 Oct 2020 16:58:12
	(b) (4)	
User entered 'ug (ug)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:06
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:11
User entered 'twice daily (BID)' reason for change: Data Entry Error	marissa Mueller (b) (4)	01 Aug 2020 20:50:38
	(b) (4)	
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:14
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:17
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:29
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:26
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		03 Aug 2020 13:42:37
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:49:45
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:49:42
User entered 'un UNK 2019'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:21
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:32
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:34
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:36
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:49:42
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Aug 2020 20:50:38
User entered '1'	System	01 Aug 2020 20:49:42

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:49:42

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:49:42

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:47
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:16:11
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:16:11
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 21:01:56
Data point term sent to Coder	System	01 Aug 2020 20:50:43
User entered 'oxybutynin patch'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:49
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:51
User entered 'overactive bladder'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:55
User entered '3.9'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:50:58
User entered 'mg (mg)'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:00
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:02
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:07
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:09
User entered 'Transdermal (TRANSDERMAL)' reason for change: Data Entry Error	marissa Mueller (b) (4)	01 Aug 2020 21:01:38
	(b) (4)	
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:11
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:13
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		03 Aug 2020 13:42:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:50:25
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:50:21
User entered 'un UNK 2016'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:17
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:22
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:24
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:27
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:50:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:50:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:50:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:50:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 19:50:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 19:50:48
	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 19:50:33
Coding entries removed.	Colton King (b) (4)	09 Sep 2020 19:50:30
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Aug 2020 20:52:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Aug 2020 20:52:17
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:51:44
User entered 'acetaminophen'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:42
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:45
	(b) (4), (b) (6)	
User closed query 'Per CDM: Per DM CLR re-query on Medical History eCRF: Please update the reason for medication to specify the type of the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid) and ensure it matches the condition in the Medical History eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 06:48:59
Query 'Per CDM: Per DM CLR re-query on Medical History eCRF: Please update the reason for medication to specify the type of the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid) and ensure it matches the condition in the Medical History eCRF. ' answered with 'Updated ' (Site from DM).	Colton King (b) (4) (b) (4)	09 Sep 2020 19:50:44
User entered 'GENERALIZED ARTHRITIS, UNSPECIFIED, NON AUTOIMMUNE' reason for change: Data Entry Error	Colton King (b) (4) (b) (4)	09 Sep 2020 19:50:30
User opened query 'Per CDM: Per DM CLR re-query on Medical History eCRF: Please update the reason for medication to specify the type of the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid) and ensure it matches the condition in the Medical History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:33:40
Query 'Per CDM: Per CLR re-query on Medical History eCRF: Please update the reason for medication to specify the type of the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid) and ensure it matches the condition in the Medical History eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:33:28
User opened query 'Per CDM: Per CLR re-query on Medical History eCRF: Please update the reason for medication to specify the type of the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid) and ensure it matches the condition in the Medical History eCRF.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 12:32:29

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please update the reason for medication to specify the type of the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid) and ensure it matches the condition in the Medical History eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 12:31:45
User opened query 'Per CDM: Please update the reason for medication to specify the type of the type of ARTHRITIS (psoriatic, osteoarthritis or rheumatoid) and ensure it matches the condition in the Medical History eCRF.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:52:31
User entered 'generalized arthritis'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:48
User entered '500'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:51
User entered 'mg (mg)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:55
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:51:59
User entered 'twice daily (BID)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:02
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:04
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:06
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:13
	(b) (4), (b) (6)	20 Aug 2020 07:32:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	19 Aug 2020 20:25:19
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 20:25:12
User entered 'UN UNK 1993' reason for change: New Information	Janna Martinez (b) (4)	19 Aug 2020 20:25:12
	(b) (4)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 13:42:46
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:51:13
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:51:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 1980'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:15
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:17
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:21
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:23
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Aug 2020 20:51:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:51:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:51:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:47
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.	Coder Import (b) (4)	01 Aug 2020 20:54:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 20:54:18
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:52:46
User entered 'levothyroxine'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:49
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:51
User entered 'hypothyroidism'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '175'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'ug (ug)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 07:36:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	19 Aug 2020 20:30:29
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 20:27:50
User entered 'UN UNK 2000' reason for change: Data Entry Error	Janna Martinez (b) (4)	19 Aug 2020 20:27:50
	(b) (4)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 13:42:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:51:54
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:51:52

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 1980'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:51:52
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:51:52

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:51:52

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:51:52

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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.	Coder Import (b) (4)	03 Aug 2020 09:34:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 09:34:01
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 21:02:57
Data point term sent to Coder	System	01 Aug 2020 20:52:46
User entered 'glipizide'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'TYPE II DIABETES MELLITUS' reason for change: Data Entry Error	marissa Mueller (b) (4)	01 Aug 2020 21:02:00
	(b) (4)	
User entered 'type II diabetes mellitus'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '5'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 13:42:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:52:28
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:52:26
User entered 'un UNK 2000'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:52:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:52:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:52:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:52:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 19:44:46
	(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 19:44:46
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 19:44:08
Coding entries removed.	Janna Martinez (b) (4)	28 Aug 2020 19:43:51
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 13:05:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 13:05:09
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:53:47
User entered 'lovastatin'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4), (b) (6)	
User closed query 'Per MM, Please revise the indication ' (Site from DM).		09 Oct 2020 07:06:22
Query 'Per MM, Please revise the indication ' answered with 'Correct as entered. The medication Lovastatin is being taken for Hypercholesterolemia, per subject's verbal report at Screening visit, and as entered to this eCRF.' (Site from DM).	Sherry Henning (b) (4)	08 Oct 2020 14:21:01
	(b) (4)	
User opened query 'Per MM, Please revise the indication ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:41:03
User entered 'HYPERCHOLESTEROLEMIA' reason for change: Data Entry Error	Janna Martinez (b) (4)	28 Aug 2020 19:43:51
	(b) (4)	
User entered 'hypcholesterolemia'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '20'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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) (6)	16 Sep 2020 07:50:24
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 per source' (Site from DM).	marissa Mueller (b) (4)	15 Sep 2020 00:28:22
User entered '03 Aug 2009' reason for change: Data Entry Error	(b) (4)	
	(b) (4)	
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)	10 Sep 2020 04:54:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 13:42:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at randomization ' (Site from System).	marissa Mueller (b) (4)	01 Aug 2020 20:53:05
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:53:02
User entered 'un UNK 1990'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:53:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:53:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:53:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:53:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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.	Coder Import (b) (4)	03 Aug 2020 13:12:05
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 13:12:05
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:54:52
User entered 'metformin'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'type II diabetes mellitus'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:09
User closed query 'please verify as 2000 as per CM log' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:33:04
Query 'please verify as 2000 as per CM log' answered with 'Conmed log reflects 1000mg BID' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 12:23:38
User opened query 'please verify as 2000 as per CM log' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:54:44
DataPoint Un-verified.		23 Oct 2020 19:54:23
DataPoint Verified.		23 Oct 2020 19:52:59
User entered '1000'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'twice daily (BID)'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		03 Aug 2020 13:43:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:54:09
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:54:07
User entered 'un UNK 2000'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:54:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Aug 2020 20:54:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:54:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:54:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 20:56:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 20:56:05
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:55:53
User entered 'oxybutinin'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'overactive bladder'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '10'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'twice daily (BID)'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		03 Aug 2020 13:43:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:58:59
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:55:04
User entered 'un UNK 2005'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:55:04
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Aug 2020 20:55:04

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:55:04

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:55:04

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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)	01 Aug 2020 21:01:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 21:01:06
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 20:59:55
User entered 'aspirin'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cardiac prophylaxis'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '81'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		03 Aug 2020 13:43:14
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 20:59:38
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 20:59:36
User entered 'un UNK 2010'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 20:59:36
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:59:36

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 20:59:36

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 20:59:36

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ZINGIBER OFFICINALE ROOT, PRODUCTSYNONYM: GINGER ROOT [ZINGIBER OFFICINALE ROOT] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 11:12:08
	(b) (4)	
User coded data point as Term Coded data point by User (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 11:12:08
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 21:00:56
User entered 'ginger root'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4), (b) (6)	
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).		16 Sep 2020 08:09:05
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	15 Sep 2020 00:29:29
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Sep 2020 00:29:26
	(b) (4)	
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:25:12
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'nutritional supplement'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'I'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'tablet (TABLET)'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		03 Aug 2020 13:43:18
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	marissa Mueller (b) (4)	01 Aug 2020 21:00:26
answered with 'ongoing at randomization ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 21:00:22
User entered 'un UNK 2018'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 21:00:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 21:00:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 21:00:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 21:00:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:15:49
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:15:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Aug 2020 21:02:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Aug 2020 21:02:05
Data point term sent to Coder	System	01 Aug 2020 21:00:56
User entered 'iron'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 08:09:18
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	15 Sep 2020 00:29:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 00:29:33
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:25:25
User entered 'No (N)'	marissa Mueller (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'nutritional supplement'	marissa Mueller (b) (4)	01 Aug 2020 21:00:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '65'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4)	01 Aug 2020 21:00:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 21:00:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 13:43:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at randomization ' (Site from System).	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 21:00:51
User entered 'un UNK 2000'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:26:34
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 12:26:05
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 20:14:46
DataPoint Verified.		23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	01 Aug 2020 21:00:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'please verify as 9/21/2020 as per CM log' (Site from CRA).	(b) (4)	04 Nov 2020 18:26:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:26:31
Query 'please verify as 9/21/2020 as per CM log' answered with 'updated' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 12:26:13
User entered '21 Sep 2020' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 12:26:05
User opened query 'please verify as 9/21/2020 as per CM log' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 20:15:07
DataPoint Un-verified.		23 Oct 2020 20:14:48
DataPoint Verified.		23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	01 Aug 2020 21:00:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User entered '1'	System	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User entered '1'	System	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:27
User entered '804 (804)'	System	01 Aug 2020 21:00:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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.	Coder Import (b) (4) (b) (4)	29 Aug 2020 00:07:47
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 00:07:47
Data point term sent to Coder	System	28 Aug 2020 19:45:14
User entered 'LISINOPRIL'	Janna Martinez (b) (4) (b) (4)	28 Aug 2020 19:45:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review indication. It is not listed on either Medical History (ongoing) or Adverse Event page. Reconcile and update as appropriate.		16 Sep 2020 08:08:25
' (Site from DM).		
Query 'Per DM CLR: Please review indication. It is not listed on either Medical History (ongoing) or Adverse Event page. Reconcile and update as appropriate.	marissa Mueller (b) (4)	15 Sep 2020 00:28:55
	(b) (4)	
' answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: Please review indication. It is not listed on either Medical History (ongoing) or Adverse Event page. Reconcile and update as appropriate.	(b) (4), (b) (6)	12 Sep 2020 06:19:31
' (Site from DM).		
User entered 'HYPERTENSTION'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

fb

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '10'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '07 Aug 2020'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Janna Martinez (b) (4)	28 Aug 2020 19:45:07
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 19:45:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 19:45:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 19:45:07

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 23:13:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 23:13:42
Data point term sent to Coder	System	24 Sep 2020 21:28:46
User entered 'keflex'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '500'	marissa Mueller (b) (4)	24 Sep 2020 21:28:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:28:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'four times daily (QID)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	24 Sep 2020 21:28:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:28:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:17:56
User entered '21 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	04 Nov 2020 23:25:26
DataPoint Un-verified.	(b) (4) marissa Mueller (b) (4)	04 Nov 2020 23:25:17
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	04 Nov 2020 23:25:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '21 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:28:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:26:10
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 12:26:42
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 19:56:28
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 21:28:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'please verify as 23Sep as per CM log' (Site from CRA).	(b) (4)	05 Nov 2020 14:21:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:17:56
Query 'please verify as 23Sep as per CM log' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	04 Nov 2020 23:25:30
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	04 Nov 2020 23:25:26
User entered '23 Sep 2020' reason for change: Data Entry Error	System	04 Nov 2020 23:25:26
User opened query 'End date is prior to start date. Please correct.' (Site from System).	marissa Mueller (b) (4)	04 Nov 2020 23:25:26
User opened query 'please verify as 23Sep as per CM log' (Site from CRA).	(b) (4)	04 Nov 2020 23:25:17
User closed query 'please verify stop date as 23Sep20 as per source' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:26:03
Query 'please verify stop date as 23Sep20 as per source' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:26:03
User entered '21 Sep 2020' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 12:26:50
User opened query 'please verify stop date as 23Sep20 as per source' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 12:26:42
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 19:56:59
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:56:38
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	marissa Mueller (b) (4)	24 Sep 2020 21:28:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User entered '4'	System	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User entered '1'	System	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:51
User entered '804 (804)'	System	24 Sep 2020 21:28:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 06:03:33
User coded data point as Term Coded data point by User (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 06:03:33
Data point term sent to Coder	System	02 Oct 2020 21:16:48
Coding entries removed.	Janna Martinez (b) (4) (b) (4)	02 Oct 2020 21:16:27
User entered 'BACTRIM DS, trimethoprim and sulfamethoxazole' reason for change: Data Entry Error	Janna Martinez (b) (4) (b) (4)	02 Oct 2020 21:16:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:30:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:30:45
Data point term sent to Coder	System	24 Sep 2020 21:29:47
User entered 'bactrim DS'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
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) (6)	05 Oct 2020 08:07:50
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 'data corrected' (Site from DM).	Janna Martinez (b) (4)	02 Oct 2020 21:16:42
User entered '160/800' reason for change: Data Entry Error	(b) (4)	
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).	Janna Martinez (b) (4)	02 Oct 2020 21:16:27
User entered '800'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 09:17:23
	marissa Mueller (b) (4)	24 Sep 2020 21:29:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'twice daily (BID)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:29:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:29:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '21 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:24:40
User entered 'No (N)' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 12:27:57
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 19:57:23
DataPoint Verified.		23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'please verify as 23Sep2020 as per source' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:24:50
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:24:37
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	24 Oct 2020 12:27:57
Query 'please verify as 23Sep2020 as per source' answered with 'updated' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 12:27:26
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	24 Oct 2020 12:27:18
User entered '23 Sep 2020' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 12:27:18
User opened query 'please verify as 23Sep2020 as per source' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:57:42
DataPoint Un-verified.		23 Oct 2020 19:57:24
DataPoint Verified.		23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:29:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 21:29:02
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User entered '2'	System	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User entered '1'	System	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:53
User entered '804 (804)'	System	24 Sep 2020 21:29:02

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:10:49
User coded data point as Term Coded data point by User (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:10:49
Data point term sent to Coder	System	30 Sep 2020 20:51:12
User entered 'ZITHROMAX'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'CELLULITIS LEFT KNEE'	Janna Martinez (b) (4)	30 Sep 2020 20:50:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '500'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	09 Oct 2020 23:00:30
User entered '25 Sep 2020'	(b) (4) Janna Martinez (b) (4)	30 Sep 2020 20:50:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Janna Martinez (b) (4)	30 Sep 2020 20:50:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	09 Oct 2020 23:00:30
User entered '25 Sep 2020'	(b) (4) Janna Martinez (b) (4)	30 Sep 2020 20:50:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User entered empty.	System	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User entered empty.	System	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:06:59
User entered empty.	System	30 Sep 2020 20:50:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:10:49
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:10:49
Data point term sent to Coder	System	30 Sep 2020 20:52:12
User entered 'ZITHROMAX'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Janna Martinez (b) (4)	30 Sep 2020 20:51:41
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'CELLULITIS LEFT KNEE'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '250'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '25 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	09 Oct 2020 23:00:53
User entered '26 Sep 2020'	(b) (4) Janna Martinez (b) (4)	30 Sep 2020 20:51:41
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '29 Sep 2020'	Janna Martinez (b) (4)	30 Sep 2020 20:51:41
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User entered '1'	System	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User entered '1'	System	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:02
User entered '804 (804)'	System	30 Sep 2020 20:51:41

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:38:33
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:38:33
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
Data point term sent to Coder	System	16 Oct 2020 17:01:46
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	16 Oct 2020 17:01:30
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated' (Site from System).	marissa Mueller (b) (4)	16 Oct 2020 17:01:30
User entered 'LOVENOX (enoxaparin sodium)' reason for change: Data Entry Error	marissa Mueller (b) (4)	16 Oct 2020 17:01:23
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	12 Oct 2020 13:43:13
Data point term sent to Coder	System	09 Oct 2020 23:02:43
User entered 'lovenox'	marissa Mueller (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'celluitus left knee'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '40'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4)	09 Oct 2020 23:01:46
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:01:46
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Subcutaneous (SUBCUTANEOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '23 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:01:46
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '23 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:01:46
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User entered empty.	System	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User entered empty.	System	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:30
User entered empty.	System	09 Oct 2020 23:01:46

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 23:03:30
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 Oct 2020 23:03:30
Data point term sent to Coder	System	09 Oct 2020 23:02:43
User entered 'tylenol'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:02:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '650'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:02:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '22 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	10 Feb 2021 15:23:31
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	10 Feb 2021 15:23:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	09 Oct 2020 23:02:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	10 Feb 2021 15:23:31
	(b) (4)	
User entered '11 Oct 2020' reason for change: New Information	Riley King (b) (4)	10 Feb 2021 15:23:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:02:26
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	23 Oct 2020 19:52:59
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:02:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 23:02:30
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	09 Oct 2020 23:02:30
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:02:26
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User entered empty.	System	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User entered empty.	System	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:34
User entered empty.	System	09 Oct 2020 23:02:26

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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)	09 Oct 2020 23:04:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 23:04:24
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 23:03:44
User entered 'ferrous sulfate'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'nutritional supplement'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '325'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '22 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:03:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 23:03:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 23:03:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 23:03:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	04 Nov 2020 17:56:07
User closed query 'please correct spelling to vancomycin' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:56:05
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)	25 Oct 2020 04:32:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	(b) (4)	25 Oct 2020 04:32:42
Data point term sent to Coder	System	24 Oct 2020 12:29:48
Query 'please correct spelling to vancomycin' answered with 'corrected' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 12:29:00
Coding entries removed.	Jeri King (b) (4)	24 Oct 2020 12:28:51
User entered 'VANCOMYCIN' reason for change: Data Entry Error	Jeri King (b) (4)	24 Oct 2020 12:28:51
User opened query 'please correct spelling to vancomycin' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 20:00:34
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 20:00:13
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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)	10 Oct 2020 04:59:19
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	(b) (4)	10 Oct 2020 04:59:19
Data point term sent to Coder	System	09 Oct 2020 23:04:44

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
User entered 'vacomycin'	marissa Mueller (b) (4)	09 Oct 2020 23:04:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:04:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 23:04:28
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:28
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:04:22
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4)	09 Oct 2020 23:04:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '1500'	marissa Mueller (b) (4)	09 Oct 2020 23:04:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	09 Oct 2020 23:04:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:04:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '22 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:04:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User entered '1'	System	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User entered '1'	System	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:40
User entered '804 (804)'	System	09 Oct 2020 23:04:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 17:49:58
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 04:40:15
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 23:05:45
User entered 'normal saline'	marissa Mueller (b) (4)	09 Oct 2020 23:04:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'dehydration'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '1000'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mL (mL)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	09 Oct 2020 23:04:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	09 Oct 2020 23:04:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:04:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '22 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:04:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:04:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '25 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:04:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User entered empty.	System	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User entered empty.	System	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:47
User entered empty.	System	09 Oct 2020 23:04:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:49:58
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:49:58
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:40:15
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:40:15
Data point term sent to Coder	System	09 Oct 2020 23:06:47
User entered 'normal saline'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '100'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mL (mL)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	09 Oct 2020 23:06:53
User entered 'other (OTHER)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:53
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	09 Oct 2020 23:06:39
User entered 'once daily (QD)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'every hour'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '23 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:06:39
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '23 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User entered empty.	System	09 Oct 2020 23:06:53
User entered '1'	System	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User entered empty.	System	09 Oct 2020 23:06:53
User entered '1'	System	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:52
User entered empty.	System	09 Oct 2020 23:06:53
User entered '804 (804)'	System	09 Oct 2020 23:06:39

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:53:18
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:53:18
Data point term sent to Coder	System	09 Oct 2020 23:07:51
User entered 'clindamycin'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4)	09 Oct 2020 23:07:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '600'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:07:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	marissa Mueller (b) (4)	09 Oct 2020 23:07:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:07:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '22 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:07:22
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '23 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User entered '1'	System	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User entered '1'	System	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:07:58
User entered '804 (804)'	System	09 Oct 2020 23:07:22

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 23:09:25
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 Oct 2020 23:09:25
Data point term sent to Coder	System	09 Oct 2020 23:08:52
User entered 'zosyn'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '3.375'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:07:56
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'other (OTHER)'	marissa Mueller (b) (4)	09 Oct 2020 23:07:56
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'Per CDM (re-Query):kindly review and update the data appropriately. Select an option from the drop down by calculating the time subject is awake.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:49:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
Query 'Per CDM (re-Query):kindly review and update the data appropriately. Select an option from the drop down by calculating the time subject is awake.' answered with 'This is given even when subject is sleeping. It's an IV medication given by hospital staff every 6 hours and not QID.' (Site from DM).	Jeri King (b) (4)	23 Oct 2020 17:19:47
User opened query 'Per CDM (re-Query):kindly review and update the data appropriately. Select an option from the drop down by calculating the time subject is awake.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:00:41
User closed query 'Per CDM: As a frequency of administration "EVERY 6 HOURS" has been entered Please review if one of the available options from the drop-down list might be applicable (e.g. four times daily). Please update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:00:41
Query 'Per CDM: As a frequency of administration "EVERY 6 HOURS" has been entered. Please review if one of the available options from the drop-down list might be applicable (e.g. four times daily). Please update as appropriate, else clarify. ' answered with 'correct as entered as given every 6 hours, not just 4X daiky while awake' (Site from DM).	marissa Mueller (b) (4) (b) (4)	16 Oct 2020 17:00:28
User opened query 'Per CDM: As a frequency of administration "EVERY 6 HOURS" has been entered Please review if one of the available options from the drop-down list might be applicable (e.g. four times daily). Please update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:49:50

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'every 6 hours'	marissa Mueller (b) (4)	09 Oct 2020 23:07:56
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	09 Oct 2020 23:07:56
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:07:56
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '23 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '23 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User entered empty.	System	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User entered empty.	System	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:07
User entered empty.	System	09 Oct 2020 23:07:56

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	23 Oct 2020 19:52:59
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 Oct 2020 23:09:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 23:09:25
Data point term sent to Coder	System	09 Oct 2020 23:08:54
User entered 'influenza vaccine'	marissa Mueller (b) (4)	09 Oct 2020 23:08:30
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	09 Oct 2020 23:08:30
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'influenza prophylaxis'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:08:30

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0.5'	marissa Mueller (b) (4)	09 Oct 2020 23:08:30

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mL (mL)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:08:30

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:08:30

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4)	09 Oct 2020 23:08:30
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:08:30
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intramuscular (INTRAMUSCULAR)'	marissa Mueller (b) (4)	09 Oct 2020 23:08:30
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:08:30
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:08:30

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:08:30
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:08:30
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:08:30
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:08:30

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User entered empty.	System	09 Oct 2020 23:08:30

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User entered empty.	System	09 Oct 2020 23:08:30

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:11
User entered empty.	System	09 Oct 2020 23:08:30

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: DUONEB - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:00:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:00:21
Data point term sent to Coder	System	09 Oct 2020 23:09:54
User entered 'duoNeb'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'asthma-mild'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'I'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Other (OTHER)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'unit'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Other (OTHER)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'nebulizer'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '22 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:09:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User entered empty.	System	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User entered empty.	System	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:15
User entered empty.	System	09 Oct 2020 23:09:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: DAPTOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:55:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:55:20
Data point term sent to Coder	System	09 Oct 2020 23:10:55
User entered 'daptomycin'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '750'	marissa Mueller (b) (4)	09 Oct 2020 23:10:15
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:10:15
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'other (OTHER)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'Per CDM (re-Query): kindly review and update the data appropriately. Select an option from the drop down by calculating the time subject is awake. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:50:25
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
Query 'Per CDM (re-Query): kindly review and update the data appropriately. Select an option from the drop down by calculating the time subject is awake. ' answered with 'This is given by hospital staff every 6 hours even when subject is sleeping intravenously. The correct time is every 6 hours and not QID' (Site from DM).	Jeri King (b) (4)	23 Oct 2020 17:20:38
User opened query 'Per CDM (re-Query): kindly review and update the data appropriately. Select an option from the drop down by calculating the time subject is awake. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:04:02
User closed query 'Per CDM: As a frequency of administration "EVERY 6 HOURS" has been entered Please review if one of the available options from the drop-down list might be applicable (e.g. four times daily). Please update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:04:02
Query 'Per CDM: As a frequency of administration "EVERY 6 HOURS" has been entered. Please review if one of the available options from the drop-down list might be applicable (e.g. four times daily). Please update as appropriate, else clarify. ' answered with 'correct as entered as was given every 6 hours, not 4X daily while awake' (Site from DM).	marissa Mueller (b) (4) (b) (4)	16 Oct 2020 16:59:12
User opened query 'Per CDM: As a frequency of administration "EVERY 6 HOURS" has been entered Please review if one of the available options from the drop-down list might be applicable (e.g. four times daily). Please update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:50:01

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'every 6 hours'	marissa Mueller (b) (4)	09 Oct 2020 23:10:15
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '25 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User entered empty.	System	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User entered empty.	System	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:20
User entered empty.	System	09 Oct 2020 23:10:15

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:36:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:36:20
Data point term sent to Coder	System	09 Oct 2020 23:10:55
User entered 'lispro'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'diabetes mellitus II'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'I'	marissa Mueller (b) (4)	09 Oct 2020 23:10:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Other (OTHER)'	marissa Mueller (b) (4)	09 Oct 2020 23:10:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'unit'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:10:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Subcutaneous (SUBCUTANEOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '23 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:10:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:10:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:10:51
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User entered empty.	System	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User entered empty.	System	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:24
User entered empty.	System	09 Oct 2020 23:10:51

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	23 Oct 2020 19:52:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: DEXTROMETHORPHAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 03:57:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 03:57:21
Data point term sent to Coder	System	09 Oct 2020 23:11:56
User entered 'dextromethorphan'	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'chronic cough'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '30'	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '23 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:11:21
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User entered empty.	System	09 Oct 2020 23:11:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User entered empty.	System	09 Oct 2020 23:11:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:46
User entered empty.	System	09 Oct 2020 23:11:21

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
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)	10 Oct 2020 04:34:19
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:34:19
Data point term sent to Coder	System	09 Oct 2020 23:12:56
User entered 'lasix'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:11:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'edema bilateral lower extremity'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '40'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:11:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:11:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '25 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:11:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '25 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User entered empty.	System	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User entered empty.	System	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:50
User entered empty.	System	09 Oct 2020 23:11:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:08:25
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:08:25
Data point term sent to Coder	System	09 Oct 2020 23:12:56
User entered 'hydrocodone/acetaminophen 5mg/325mg'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'I'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'tablet (TABLET)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	09 Oct 2020 23:12:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:12:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	10 Feb 2021 15:20:16
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	10 Feb 2021 15:20:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	marissa Mueller (b) (4)	09 Oct 2020 23:12:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	10 Feb 2021 15:20:16
	(b) (4)	
User entered '11 Oct 2020' reason for change: New Information	Riley King (b) (4)	10 Feb 2021 15:20:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:12:28
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User entered empty.	System	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User entered empty.	System	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:08:56
User entered empty.	System	09 Oct 2020 23:12:28

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:41:16
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:41:16
Data point term sent to Coder	System	09 Oct 2020 23:13:57
User entered 'ondansetron'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:12:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'nausea'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '4'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:12:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:12:57
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User entered empty.	System	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User entered empty.	System	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:02
User entered empty.	System	09 Oct 2020 23:12:57

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:02:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:02:23
Data point term sent to Coder	System	09 Oct 2020 23:13:57
User entered 'fentanyl'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:13:24
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '25'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	23 Oct 2020 19:52:59
User entered 'ug (ug)'	marissa Mueller (b) (4)	09 Oct 2020 23:13:24
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:13:24
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:13:24
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User entered empty.	System	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User entered empty.	System	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:07
User entered empty.	System	09 Oct 2020 23:13:24

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:51:17
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:51:17
Data point term sent to Coder	System	09 Oct 2020 23:13:57
User entered 'cefazolin'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'I'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'g (g)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:13:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4)	09 Oct 2020 23:13:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:13:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:13:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:13:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:13:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User entered empty.	System	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User entered empty.	System	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:13
User entered empty.	System	09 Oct 2020 23:13:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SUGAMMADEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:54:14
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:54:14
Data point term sent to Coder	System	09 Oct 2020 23:14:58
User entered 'sugammadex'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4)	09 Oct 2020 23:14:40
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '200'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:14:40
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:14:40
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User entered empty.	System	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User entered empty.	System	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:19
User entered empty.	System	09 Oct 2020 23:14:40

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:57:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:57:21
Data point term sent to Coder	System	09 Oct 2020 23:15:58
User entered 'dexamethasone'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '10'	marissa Mueller (b) (4)	09 Oct 2020 23:15:03
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	09 Oct 2020 23:15:03
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:15:03
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:15:03
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	09 Oct 2020 23:15:03
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:15:03
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:15:03
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:15:03
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User entered empty.	System	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User entered empty.	System	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:23
User entered empty.	System	09 Oct 2020 23:15:03

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:49:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:49:21
Data point term sent to Coder	System	09 Oct 2020 23:15:58
User entered 'rocuronium'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User closed query 'please verify as general anesthesia' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:54:17
DataPoint Verified.		04 Nov 2020 17:54:15
Query 'please verify as general anesthesia' answered with 'Confirmed - given during procedure' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 12:30:09
User opened query 'please verify as general anesthesia' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 20:07:22
DataPoint Un-verified.		23 Oct 2020 20:07:05
DataPoint Verified.		23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4)	09 Oct 2020 23:15:27
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '50'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:15:27
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4)	09 Oct 2020 23:15:27
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:15:27
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User entered empty.	System	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User entered empty.	System	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:28
User entered empty.	System	09 Oct 2020 23:15:27

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: CHOLINE DERIVATIVES, PRODUCT: SUXAMETHONIUM, PRODUCTSYNONYM: SUCCINYLCHOLINE [SUXAMETHONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 04:54:14
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 04:54:14
Data point term sent to Coder	System	09 Oct 2020 23:15:59
User entered 'succinylcholine'	marissa Mueller (b) (4)	09 Oct 2020 23:15:54
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:52:35
User closed query 'please verify as general anesthesia' (Site from CRA).		04 Nov 2020 17:52:33
Query 'please verify as general anesthesia' answered with 'Confirmed - given during procedure' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 12:30:33
User opened query 'please verify as general anesthesia' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 20:07:56
DataPoint Un-verified.		23 Oct 2020 20:07:32
DataPoint Verified.		23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4)	09 Oct 2020 23:15:54
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '160'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	09 Oct 2020 23:15:54
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	09 Oct 2020 23:15:54
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:15:54
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:15:54
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:15:54
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:15:54
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User entered empty.	System	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User entered empty.	System	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:35
User entered empty.	System	09 Oct 2020 23:15:54

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Oct 2020 23:18:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Oct 2020 23:18:42
Data point term sent to Coder	System	09 Oct 2020 23:17:00
User entered 'diprivan'	marissa Mueller (b) (4)	09 Oct 2020 23:16:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:52:14
DataPoint Un-verified.		23 Oct 2020 20:08:19
DataPoint Verified.		23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4)	09 Oct 2020 23:16:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'I'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	09 Oct 2020 23:16:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:16:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:16:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:16:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User entered empty.	System	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User entered empty.	System	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:42
User entered empty.	System	09 Oct 2020 23:16:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	23 Oct 2020 19:52:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 04:35:35
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 04:35:35
Data point term sent to Coder	System	09 Oct 2020 23:17:01
User entered 'lidocaine'	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '5'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:49

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:49

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:49

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:16:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 23:16:53
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:53
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 23:16:49
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:49

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:16:49
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:16:49

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User entered empty.	System	09 Oct 2020 23:16:49

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User entered empty.	System	09 Oct 2020 23:16:49

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:48
User entered empty.	System	09 Oct 2020 23:16:49

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: HYOSCINE, PRODUCTSYNONYM: SCOPOLAMINE [HYOSCINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Nov 2020 09:28:10
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:28:10
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
Data point term sent to Coder	System	09 Oct 2020 23:18:03
User entered 'scopolamine'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:27:25
User closed query 'please verify as general anesthesia' (Site from CRA).		04 Nov 2020 17:27:23
Query 'please verify as general anesthesia' answered with 'Not general anesthesia but given during procedure' (Site from CRA).	Jeri King (b) (4)	24 Oct 2020 12:31:07
User opened query 'please verify as general anesthesia' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 20:09:57
DataPoint Un-verified.		23 Oct 2020 20:09:43
DataPoint Verified.		23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4)	09 Oct 2020 23:17:25
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '1.5'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	09 Oct 2020 23:17:25
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:17:25
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Topical (TOPICAL)'	marissa Mueller (b) (4)	09 Oct 2020 23:17:25
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:17:25
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:17:25
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4)	09 Oct 2020 23:17:25
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User entered empty.	System	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User entered empty.	System	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:09:57
User entered empty.	System	09 Oct 2020 23:17:25

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4)	23 Oct 2020 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 03:51:18
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 03:51:18
Data point term sent to Coder	System	09 Oct 2020 23:18:01
User entered 'ceftriaxone'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cellulitis left knee'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '2000'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once (ONCE)'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	09 Oct 2020 23:17:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	marissa Mueller (b) (4)	09 Oct 2020 23:17:55
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User entered empty.	System	09 Oct 2020 23:17:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User entered empty.	System	09 Oct 2020 23:17:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:10:05
User entered empty.	System	09 Oct 2020 23:17:55

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:20:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:20:47
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 20:46:34
Coding entries removed.	marissa Mueller (b) (4)	15 Dec 2020 20:46:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 19:04:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 19:04:36
	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 19:04:21
User entered 'Fluticasone'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:49:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 08:09:23
DataPoint Un-verified.	marissa Mueller (b) (4)	15 Dec 2020 20:46:24
User entered 'ALLERGIC RHINITIS, seasonal' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	15 Dec 2020 20:46:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated med history' (Site from DM).	(b) (4) marissa Mueller (b) (4)	15 Dec 2020 20:46:19
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 15:06:51
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'allergic rhinitis'	Sherry Henning (b) (4) (b) (4)	23 Oct 2020 19:04:00

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:49:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4)	23 Feb 2021 09:09:09
Query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'new information provided ' (Site from DM).	Cayla Lawless (b) (4)	22 Feb 2021 18:20:48
DataPoint Un-verified.	Cayla Lawless (b) (4)	22 Feb 2021 18:20:38
User entered '50' reason for change: New Information	Cayla Lawless (b) (4)	22 Feb 2021 18:20:38
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of spray 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)	28 Jan 2021 04:37:06
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '1'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:49:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Un-verified.	Janna Martinez (b) (4)	01 Mar 2021 17:22:33
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Janna Martinez (b) (4)	01 Mar 2021 17:22:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Other (OTHER)'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:49:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'Per CDM: Please note that ug (for microgram) is one of the available options from the drop-down list provided for Dose unit. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 05:33:24
Query 'Per CDM: Please note that ug (for microgram) is one of the available options from the drop-down list provided for Dose unit. Review and update as appropriate. ' answered with 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4) (b) (4)	01 Mar 2021 17:22:43
User entered empty; reason for change New Information	Janna Martinez (b) (4) (b) (4)	01 Mar 2021 17:22:33
User opened query 'Per CDM: Please note that ug (for microgram) is one of the available options from the drop-down list provided for Dose unit. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:29:49
DataPoint Un-verified.	Cayla Lawless (b) (4) (b) (4)	22 Feb 2021 18:20:38
User entered 'mcg' reason for change: New Information	Cayla Lawless (b) (4) (b) (4)	22 Feb 2021 18:20:38
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'spray'	Sherry Henning (b) (4) (b) (4)	23 Oct 2020 19:04:00

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'as needed (PRN)'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Nasal (NASAL)'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4)	23 Oct 2020 19:04:00
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:04:00

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:04:00

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:04:00

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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)	23 Oct 2020 19:06:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 19:06:39
	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 19:05:23
User entered 'Aspirin'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Yes (Y)'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'cardiac prophylaxis'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '325'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '24 Sep 2020'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '25 Sep 2020'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4)	23 Oct 2020 19:05:06
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:05:06

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:05:06

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 19:05:06

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 19:08:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 19:08:31
	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 19:07:26
User entered 'Cyanocobalamin'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:42:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 08:09:42
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	15 Dec 2020 20:47:39
DataPoint Un-verified.	marissa Mueller (b) (4) (b) (4)	15 Dec 2020 20:47:36
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	15 Dec 2020 20:47:36
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)	12 Dec 2020 15:07:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	23 Oct 2020 19:06:37

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'nutritional supplement'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '2000'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 16:54:17
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'correct as entered' (Site from DM).	marissa Mueller (b) (4)	15 Dec 2020 20:48:18
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '26 Sep 2020'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4)	23 Oct 2020 19:06:37
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:06:37

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:06:37

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 19:06:37

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERCHOLESTEROLEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 08:37:54
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERCHOLESTEROLEMIA should be recorded, and update con med indication or provide clarification. ' answered with 'normal progression of disease' (Site from DM).	marissa Mueller (b) (4)	15 Dec 2020 20:48:39
	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERCHOLESTEROLEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 15:08:07
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
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)	23 Oct 2020 19:08:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Oct 2020 19:08:31
	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 19:07:31
User entered 'Atorvastatin'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'hypercholesterolemia'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '10'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'mg (mg)'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'once daily (QD)'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered empty.	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '25 Sep 2020'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '0'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered '25 Sep 2020'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:52:59
User entered 'No (N)'	Sherry Henning (b) (4)	23 Oct 2020 19:07:23
	(b) (4)	

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:07:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:07:23

US3062019

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:03:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 19:07:23

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:03:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:39:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Jeri King (b) (4)	13 Oct 2020 18:50:22
User entered 'No (N)'	marissa Mueller (b) (4)	01 Sep 2020 19:34:12
	(b) (4)	

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:42:47
User entered '24 Sep 2020'	Jeri King (b) (4)	13 Oct 2020 18:52:31

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:42:49
User entered 'Irrigation and debridement of abscess'	Jeri King (b) (4)	13 Oct 2020 18:52:31

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:43:14
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	13 Oct 2020 18:52:31

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:43:17
User entered empty.	Jeri King (b) (4)	13 Oct 2020 18:52:31

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered '24 Sep 2020'	Jeri King (b) (4)	26 Oct 2020 20:53:30

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered 'Chest X-ray'	Jeri King (b) (4)	26 Oct 2020 20:53:30

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	26 Oct 2020 20:53:30

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered empty.	Jeri King (b) (4)	26 Oct 2020 20:53:30

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered '25 Sep 2020'	Jeri King (b) (4)	26 Oct 2020 20:53:46

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered 'Chest X-ray'	Jeri King (b) (4)	26 Oct 2020 20:53:46

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	26 Oct 2020 20:53:46

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered empty.	Jeri King (b) (4)	26 Oct 2020 20:53:46

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered '26 Sep 2020'	Jeri King (b) (4)	26 Oct 2020 20:53:58

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered 'Chest X-ray'	Jeri King (b) (4)	26 Oct 2020 20:53:58

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	26 Oct 2020 20:53:58

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered empty.	Jeri King (b) (4)	26 Oct 2020 20:53:58

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered '26 Sep 2020'	Jeri King (b) (4)	26 Oct 2020 20:54:10

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered 'Echocardiogram'	Jeri King (b) (4)	26 Oct 2020 20:54:10

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	26 Oct 2020 20:54:10

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:38:54
User entered empty.	Jeri King (b) (4)	26 Oct 2020 20:54:10

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '22 Sep 2020'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:53:00

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered 'x-ray, left knee'	Riley King (b) (4)	01 Mar 2021 17:53:00
	(b) (4)	

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:53:00

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	(b) (4) Riley King (b) (4)	01 Mar 2021 17:53:00

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '24 Sep 2020'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:53:29

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'echocardiogram'	Riley King (b) (4)	01 Mar 2021 17:53:29

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:53:29

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	Riley King (b) (4)	01 Mar 2021 17:53:29

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '22 Sep 2020'	Riley King (b) (4)	01 Mar 2021 17:53:47

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'blood culture'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:53:47

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:53:47

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:53:47

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '24 Sep 2020'	(b) (4) Riley King (b) (4)	01 Mar 2021 17:54:07

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'blood culture'	Riley King (b) (4)	01 Mar 2021 17:54:07

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Adverse Event (AE)'	Riley King (b) (4)	01 Mar 2021 17:54:07

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:54:07

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '22 Sep 2020'	Riley King (b) (4)	01 Mar 2021 17:54:29

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'fluid knee culture'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:54:29

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:54:29

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:54:29

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:03:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered '24 Sep 2020'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:54:51

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:03:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'tissue knee culture'	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:54:51

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:03:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4)	01 Mar 2021 17:54:51

US3062019

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:03:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:17:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	01 Mar 2021 17:54:51

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
User entered '25/Sep/2020 15:08'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		01 Oct 2020 12:31:42
User entered 'I'		25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
User entered '01/Oct/2020 08:31'	System	01 Oct 2020 12:31:51

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		05 Oct 2020 12:44:53
User entered 'I'		01 Oct 2020 12:31:51

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
User entered '05/Oct/2020 08:45'	System	05 Oct 2020 12:45:04

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		12 Oct 2020 15:18:46
User entered 'I'		05 Oct 2020 12:45:04

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.		01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
User entered '12/Oct/2020 11:18'	System	12 Oct 2020 15:18:54

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:59:09
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 15:18:54

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
User entered '20/Oct/2020 19:59'	System	20 Oct 2020 19:59:19

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 15:25:49
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 19:59:19

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
User entered '21/Oct/2020 15:26'	System	21 Oct 2020 15:26:01

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 15:26:06
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 15:26:01

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:49:57
User entered '26/Oct/2020 17:40'	System	26 Oct 2020 17:40:39

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:49:57
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 13:29:28
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 17:40:39

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:49:57
User entered '27/Oct/2020 09:29'	System	27 Oct 2020 13:29:37

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:34:36
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:49:57
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 13:29:37

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:49:57
User entered '03/Nov/2020 17:37'	System	03 Nov 2020 17:37:24

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:34:36
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:49:57
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 17:37:24

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered	System	25 Sep 2020 15:07:20
'USA-US090-2020-MRNA-1273-P301000003'		

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Yes (Y)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

tb

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'No (N)'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Richard'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Glover'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '700 Medical Center Dr.'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'Newton'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered 'KS'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:08:00
User entered '67114'	System	25 Sep 2020 15:07:20

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:17:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:31:42
User entered 'US'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	11 Feb 2021 14:35:19
User entered '9'	System	03 Nov 2020 17:37:24
User entered '8'	System	27 Oct 2020 13:29:37
User entered '7'	System	26 Oct 2020 17:40:39
User entered '6'	System	21 Oct 2020 15:26:01
User entered '5'	System	20 Oct 2020 19:59:19
User entered '4'	System	12 Oct 2020 15:18:54
User entered '3'	System	05 Oct 2020 12:45:04
User entered '2'	System	01 Oct 2020 12:31:51
User entered '1'	System	25 Sep 2020 15:08:08

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:03:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:46:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
	(b) (4)	
User entered '11/Feb/2021 14:35'	System	11 Feb 2021 14:35:19

US3062019

Folder: SAE USA-US090-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:03:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:46:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:12:37
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 14:35:19