

US3722066 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:32:46

All time stamps listed in this document are displayed in GMT

US3722066

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

[Participant ID](#)

US3722066

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

US3722066

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3722066

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 11:16:08

Generated On: 10 Jun 2021 09:32:46

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	68
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Mar 2021 11:16:08

Generated On: 10 Jun 2021 09:32:46

Date of Informed Consent (*dd MMM yyyy*) 3 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

US3722066

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Mar 2021 11:16:08

Generated On: 10 Jun 2021 09:32:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3722066

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	HYPERTENSION
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)	_____

US3722066

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1956
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 1956
Start Year (derived)	1956
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1956
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 1956
Start Year (derived)	1956
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	OSTEOARTHRITIS IN RIGHT KNEE AND HIP, BILATERAL THUMBS AND SHOULDERS
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3722066

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	TORE ROTATOR CUFF LEFT SHOULDER
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3722066

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	TORE ROTATOR CUFF RIGHT SHOULDER
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	ABDOMINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	CHRONIC KIDNEY DISEASE STAGE 3
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	05 MAY 2014
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)	MAY 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Condition	RHINORRHEA
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3722066

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:11 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 17:11
Height (<i>xxx.x</i>)	167 cm
Weight (<i>xxx.x</i>)	88.9 kg
BMI (<i>xxx.x</i>)	31.87637 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

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

Visit date (dd MMM yyyy)	3 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3722066

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 184495

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 ☒

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

Height	ND - Not Done
Weight	ND - Not Done

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

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)	3 AUG 2020
Time of assessment (00:00-23:59)	17:09 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 17:09
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	3 AUG 2020
Time of assessment (00:00-23:59)	18:14 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 18:14
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 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)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3722066

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

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.

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

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) 3 AUG 2020

What was the treatment time? (00:00-23:59) 17:44 (24 HR)

Treatment Date and Time (derived) 3 AUG 2020 17:44

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 AUG 2020
Collection time (00:00-23:59)	17:24 (24 HR)
Collection date and time (derived)	3 AUG 2020 17:24

US3722066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Collection date (dd MMM yyyy)			3 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:18	3 AUG 2020 17:18
Nasopharyngeal Swab 2	Yes	17:18	3 AUG 2020 17:18

US3722066

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

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

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

PC Time Stamp 03 AUG 2020 18:17

PC Open Date & Time 03 AUG 2020 18:04

PC Close Date & Time 03 AUG 2020 20:34

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

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

PC Time Stamp 03 AUG 2020 21:36

PC Open Date & Time 03 AUG 2020 21:29

PC Close Date & Time 04 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	04 AUG 2020 12:03
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	05 AUG 2020 12:07
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

06 AUG 2020 12:03

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	07 AUG 2020 12:14
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

08 AUG 2020 12:42

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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):

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

09 AUG 2020 12:02

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

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

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

PC Time Stamp 10 AUG 2020 12:14

PC Open Date & Time 10 AUG 2020 12:00

PC Close Date & Time 11 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 10

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	12 AUG 2020 13:01
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 11

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	13 AUG 2020 12:32
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 12

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

14 AUG 2020 12:13

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 13

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	15 AUG 2020 12:05
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	16 AUG 2020 12:05
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 15

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True
PC Time Stamp	17 AUG 2020 12:46
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 16

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

18 AUG 2020 12:17

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

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

03 AUG 2020 18:18

PC Open Date & Time

03 AUG 2020 18:04

PC Close Date & Time

03 AUG 2020 20:34

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

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

03 AUG 2020 21:37

PC Open Date & Time

03 AUG 2020 21:29

PC Close Date & Time

04 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

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

04 AUG 2020 12:03

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

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

05 AUG 2020 12:07

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

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

06 AUG 2020 12:03

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

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

07 AUG 2020 12:15

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

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

08 AUG 2020 12:42

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

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

09 AUG 2020 12:03

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 18:19
PC Open Date & Time	03 AUG 2020 18:04
PC Close Date & Time	03 AUG 2020 20:34

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Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

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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 ☐

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 21:37
PC Open Date & Time	03 AUG 2020 21:29
PC Close Date & Time	04 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 12:08
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 12:03
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 12:15
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:43
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:32:46

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	10 AUG 2020 12:14
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 10
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	12 AUG 2020 13:01
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 11
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	13 AUG 2020 12:32
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 12
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	14 AUG 2020 12:14
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

15 AUG 2020 12:05

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 14
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	16 AUG 2020 12:05
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 15
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	17 AUG 2020 12:46
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 16
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	18 AUG 2020 12:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3722066

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

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

Visit date (dd MMM yyyy)	28 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

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)	10:35 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 10:35
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

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)	12:21 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:21
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3722066

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

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.

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

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) 11:51 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 11:51

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

US3722066

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

11:25 (24 HR)

Collection date and time (derived)

28 AUG 2020 11:25

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

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	10:57	28 AUG 2020 10:57
Nasopharyngeal Swab 2	Yes	10:57	28 AUG 2020 10:57

US3722066

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

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

28 AUG 2020 12:21

PC Open Date & Time

28 AUG 2020 12:11

PC Close Date & Time

28 AUG 2020 14:41

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

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 15:50
PC Open Date & Time	28 AUG 2020 15:36
PC Close Date & Time	29 AUG 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

29 AUG 2020 21:06

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

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

30 AUG 2020 13:46

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

31 AUG 2020 12:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 12:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

02 SEP 2020 12:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:06

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 12:22

PC Open Date & Time

28 AUG 2020 12:11

PC Close Date & Time

28 AUG 2020 14:41

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

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 15:51

PC Open Date & Time

28 AUG 2020 15:36

PC Close Date & Time

29 AUG 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

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

29 AUG 2020 21:06

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 13:46

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

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

01 SEP 2020 12:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

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

02 SEP 2020 12:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

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

03 SEP 2020 12:06

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 12:23
PC Open Date & Time	28 AUG 2020 12:11
PC Close Date & Time	28 AUG 2020 14:41

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 15:51
PC Open Date & Time	28 AUG 2020 15:36
PC Close Date & Time	29 AUG 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

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 ☒

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 13:46
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

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
EAB) (1725)

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US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

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 ☒

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:06
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3722066

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:58:02

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	09:01 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 09:01
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722066

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3722066

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

09:38 (24 HR)

Collection date and time (derived)

25 SEP 2020 09:38

US3722066

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:58:07

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 OCT 2020 11:19:27

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

10 OCT 2020 00:07:39

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

17 OCT 2020 15:05:32

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☒

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 OCT 2020 02:13:34

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 NOV 2020 00:27:04
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 NOV 2020 09:00:32
Patient Cloud Open Date & Time	18 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
151 of 4410	

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

25 NOV 2020 11:14:19

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 DEC 2020 12:48:35
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

09 DEC 2020 00:01:44

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

16 DEC 2020 00:29:41

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

23 DEC 2020 17:13:57

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

30 DEC 2020 01:38:41

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

06 JAN 2021 01:11:08

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 03:14:16

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

20 JAN 2021 00:02:29

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

29 JAN 2021 15:03:26

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 01:40:34

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

10 FEB 2021 00:32:36

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

17 FEB 2021 00:01:25

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

24 FEB 2021 05:01:32

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

05 MAR 2021 12:10:22

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

10 MAR 2021 00:20:51

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

17 MAR 2021 01:14:12

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

24 MAR 2021 00:02:28

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

31 MAR 2021 00:30:52

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 APR 2021 00:57:20
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

14 APR 2021 00:53:26

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

21 APR 2021 01:13:47

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

28 APR 2021 00:44:43

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 341

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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="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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

Patient Cloud Open Date & Time	10 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 481

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

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

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

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

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

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

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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="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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

Patient Cloud Open Date & Time	15 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

Patient Cloud Open Date & Time	22 DEC 2021 00:01
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Patient Cloud Close Date & Time	26 DEC 2021 23:59
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US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 530

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

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

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

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

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

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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20 FEB 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

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27 FEB 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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06 MAR 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

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13 MAR 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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="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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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"/>

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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 ☐ 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 ☐

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3722066

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:32:46

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		05 MAR 2021 12:10:31

US3722066

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:15:25

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:15:25

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

SUBJECT REPORTED SOB,
FEVER OF 102.6 AND MUSCLE
ACHES. SUBJECT HAS BEEN
SCHEDULED FOR A SICK VISIT.

US3722066

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

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

Visit date (dd MMM yyyy)	3 MAR 2021
--------------------------	------------

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

Folder OID	VISIT4
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US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:48:52

Generated On: 10 Jun 2021 09:32:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:01 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 09:01
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

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.

US3722066

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 MAR 2021

Collection time (00:00-23:59)

09:09 (24 HR)

Collection date and time (derived)

3 MAR 2021 09:09

US3722066

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:16:09

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Date of Contact	16 NOV 2020
Time of Contact	15:16
Date and Time of Contact (derived)	16 NOV 2020 15:16
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Symptom Day

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

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	86 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Symptom Day

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Symptom Day

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Symptom Day

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

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Symptom Day

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

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Symptom Day

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Date of Visit 16 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 16 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 16 NOV 2020

End Date 16 NOV 2020

Oxygen Saturation 86 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒
No ☐

Date of Assessment

16 NOV 2020

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

16 NOV 2020

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	Yes	14 DEC 2020

US3722066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 15:20
Height (xxx.x)	167 cm
Weight (xxx.x)	196 lb
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722066

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3722066

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 NOV 2020

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 DEC 2020
Time of assessment (00:00-23:59)	10:02 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 10:02
Height (xxx.x)	167 cm
Weight (xxx.x)	196 lb
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 DEC 2020

US3722066

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

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

Visit date (dd MMM yyyy)	9 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
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US3722066

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Date of updated informed consent (dd MMM yyyy)	9 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	9 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3722066

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Height	
Weight	
BMI (xxx.x)	

US3722066

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 JAN 2021
Time of assessment (00:00-23:59)	13:08 (24 HR)
Vital Signs Date and Time (derived)	9 JAN 2021 13:08
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3722066

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 JAN 2021
Time of assessment (00:00-23:59)	13:44 (24 HR)
Vital Signs Date and Time (derived)	9 JAN 2021 13:44
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3722066

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 JAN 2021

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

US3722066

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 9 JAN 2021

What was the treatment time? (00:00-23:59) 13:14 (24 HR)

Treatment Date and Time (derived) 9 JAN 2021 13:14

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

US3722066

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 JAN 2021

Collection time (00:00-23:59)

12:10 (24 HR)

Collection date and time (derived)

9 JAN 2021 12:10

US3722066

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 JAN 2021

Collection time (00:00 - 23:59)

12:07

Collection Date and Time (derived)

9 JAN 2021 12:07

US3722066

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722066

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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	OLD29

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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)	6 FEB 2021
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	6 FEB 2021 08:46
Temperature (xxx.x)	99.3 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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)	6 FEB 2021
Time of assessment (00:00-23:59)	09:26 (24 HR)
Vital Signs Date and Time (derived)	6 FEB 2021 09:26
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3722066

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

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.

US3722066

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 6 FEB 2021

What was the treatment time? (00:00-23:59) 08:55 (24 HR)

Treatment Date and Time (derived) 6 FEB 2021 08:55

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

US3722066

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:48:51

Generated On: 10 Jun 2021 09:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722066

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:01 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 09:01
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722066

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

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.

US3722066

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00-23:59)	09:09 (24 HR)
Collection date and time (derived)	3 MAR 2021 09:09

US3722066

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

AEID

Adverse event

POSITIVE COVID 19

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)

11 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3722066

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

SITE RECEIVED AN EMAIL ALERT ON 15NOV2020, STATING THAT THE SUBJECT HAD COVID 19 SYMPTOMS. SUBJECT WAS CALLED ON 16NOV2020 AT 08:49 AND AT THAT TIME HE STATED THEY HAD SOB, FEVER OF UP TO 102.6, CHILLS, AND MUSCLE ACHES. SUBJECT WAS ADVISED TO GO TO ER IN THE EVENT OF AN EMERGENCY. SUBJECT EXPRESSED HE JUST THOUGHT HE HAD PNEUMONIA. PER PROTOCOL, SUBJECT WAS SCHEDULED TO COME TO SITE FOR A CONVALESCENT VISIT. UPON ARRIVING THE SUBJECT STATED THAT THEY HAD RECEIVED THEIR TEST RESULTS BACK AND THAT THEY HAD TESTED POSITIVE FOR COVID 19. HIS O2 WAS 87% AT TIME OF VISIT AND THIS WAS CONFIRMED WITH A SECOND READING. THE SUB I ONSITE CONTACTED THE PI WHO ADVISED EMS TO BE CALLED FOR PATIENT TO GO TO THE ER. AT THAT TIME 911 WAS CALLED AND THE SUBJECT WAS TRANSPORTED TO THE ER. SUBJECT WAS TAKEN TO ST. FRANCES DOWNTOWN PER SUBJECT REQUEST. SITE WILL CONTINUE TO FOLLOW UP WITH SUBJECT AS REQUIRED PER PROTOCOL.

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

US3722066

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

AEID	USA-US083-2020-MRNA-1273-P30 1000007
Adverse event	WORSENING OF COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	24 DEC 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Number of Days in ICU	8
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	

US3722066

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

RELEVANT LABS TO SAE OF
WORSENING COVID-19

- COVID-19 TEST 13 NOV 2020
(PER D/C SUMMARY) –
(POSITIVE)
- BLOOD CULTURE X 2, NO
GROWTH. COMPLETED 16 NOV
2020
- CMP 16 NOV 2020 (NA 122 L, K
3.1 L, CL 85 L, GFR EST NON-AA
54 L, CA 8.2 L, AST 41 H,
GLOBULIN 3.8 H, A-G RATIO 1.1
L)
- D-DIMER 16 NOV 2020 (0.59 H)
- BMP 17 NOV 2020 (NA 127 L, CL
93 L, GLUCOSE 115 H)
- BMP 18 NOV 2020 (NA 132 L, CL
97 L, GLUCOSE 131 H, AST 42 H,
GLOBULIN 3.9 H, A-G RATIO 1.0
L)
- CBC W DIFF 18 NOV 2020
(NEUTROPHILS 81 H)
- THYROID PANEL 20 NOV 2020
(TSH 0.096 L)
- THYROID PANEL 21 NOV 2020
(T4, FREE 1.6 H)
- CORTISOL 21 NOV 2020 (0.8 L)
(*MAY BE DUE TO
DECADRON/DEXAMETHASONE
ADMINISTRATION?)
- CBC W DIFF 21 NOV 2020 (WBC
11.5 H/NEUTROPHILS 81/ABS.
NEUTROPHILS 9.4
• BMP 21

US3722066

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

NOV 2020 (NA 136 H, GLOBULIN 3.8 H, A-G RATIO 0.9 L)

- CBC W DIFF 22 NOV 2020 (WBC 13.5 H/NEUTROPHILS 84/ABS. NEUTROPHILS 11.3, PLATELETS 483 H)
 - BMP 22 NOV 2020 (NA 136 L, GLUCOSA 105 H, GLOBULIN 3.6 H, A-G RATIO 0.9 L)
- CBC WITH DIFF 23 NOV 2020 (WBC 13.9 H/NEUTROPHILS 81/ABS. NEUTROPHILS 11.3, PLATELETS 596 H)
- BMP 23 NOV 2020 (NA 135 L, K 3.3 L, GLUCOSE 132 H, BUN 24 H)
 - CBC WITH DIFF 24 NOV 2020 (WBC 13.8 H/NEUTROPHILS 80/ABS. NEUTROPHILS 11.1, PLATELETS 640 H)
- BMP 24 NOV 2020 (NA 135 L, K 3.3 L, GLUCOSE 117 H, BUN 32 H)
 - BMP 25 NOV 2020 (NA 134 L, AGAP 4 L, BUN 29 H)
- CBC 25 NOV 2020 (WBC 14.8 H, ABS. NEUTROPHILS 11.9 H, PLATELETS 677 H)
 - D-DIMER 0.59? NO DATE, MENTIONED IN A/P
 - BNP 126H 19 DEC 2020
 - LACTIC ACID 2.2 H 19 DEC 2020
 - CBC W DIFF 19 DEC 2020 (LYMPHOCYTES 8 L)
 - CMP 19 DEC 2020 (NA 133 L, GLUCOSE 194 H, GLOBULIN 4.2

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

H, A-G RATIO 0.8 L)

SUBJECT CONFIRMED VIA
PHONE THAT HE WAS
ADMITTED TO HOSPITAL ON 16
NOV 2020. UPON RECEIPT OF
RECORDS, SUBJECT WAS
ADMITTED ON 16 NOV 2020
AND DISCHARGED ON 27 NOV
2020 AND ADMITTED AGAIN ON
19 DEC 2020 AND DISCHARGED
ON 24 DEC 2020. AFTER
REVIEW WITH PI, IT WAS
DETERMINED SAE DID NOT
TRULY RESOLVE, SO THIS IS
CONSIDERED ONE SAE.

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

US3722066

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

AEID	USA-US083-2020-MRNA-1273-P30 1000007
Adverse event	COVID-19 PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	24 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

SUBJECT CALLED THE SITE
AND INFORMED US THAT HE
WAS BACK IN THE HOSPITAL
DUE TO VIRAL PNEUMONIA
DUE TO COVID 19. SUBJECT
REPORTED THAT HE WAS
ADMITTED INTO THE
HOSPITAL ON 19DEC2020. SITE
WILL REQUEST MEDICAL
RECORDS FROM THE SUBJECT.

UPON RECEIPT OF MEDICAL
RECORDS, THE REPORT FROM
THE PATIENT WAS NOT
ACCURATE. SITE HAS UPDATE
SAES TO REFLECT THE
RECORDS.

COVID 19 POSITIVE TEST ON
11/13/2020

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

US3722066

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

AEID

Adverse event

ANXIETY SECONDARY TO
COVID 19

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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AEID

Adverse event

HYPOKALEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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	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)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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AEID	
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

AEID

Adverse event

HYPONATREMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

AEID	
Adverse event	VOLUME OVERLOAD
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:48:49

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication AMLODIPINE BESYLATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication ATORVASTAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication INDAPAMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 1.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration .112

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ROPINIROLE

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication VALSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 320

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication FLOVENT

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication IPRATROPIUM

Prophylaxis Yes ☐
No ☒

Indication RHINORRHEA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration 130

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication TYLENOL ER

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication CO-Q10

Prophylaxis Yes ☐
No ☒

Indication 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication FOR NASAL AND CHEST
CONGESTION DUE TO COVID 19

Dose per administration 1,200

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication LEXAPRO

Prophylaxis Yes ☐
No ☒

Indication ANXIETY SECONDARY TO
COVID 19

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROM

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 13

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

If dose unit is Other, specify LITER

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication AE OF COVID 19

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY RELATED TO COVID
19

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication NEUPRO

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 4/24

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPONATREMIA

Dose per administration 5-40

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

Q8H

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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		IV
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 5-40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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		IV
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q6H PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		SUPPOSITORY
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication PHENERGAN

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q6H PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication COVID 19

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

Q12H

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication DECADRON

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q24H

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication VIRAL PNEUMONIA

Dose per administration

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA DUE TO COVID 19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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		IV
Start date (dd MMM yyyy)		19 DEC 2020
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 JAN 2021
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA DUE TO COVID 19

Dose per administration 5

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

If dose unit is Other, specify LITERS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q24H

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication VITAMIN C3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication CONVALESCENT PLASMA

Prophylaxis Yes ☐
No ☒

Indication HYPONATREMIA

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING COVID 19

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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		IV
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication ESCITALOPRAM OXALATE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/> No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/> 803 <input type="radio"/> 804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication GUAIFENESIN ER

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication GUAIFENESIN ER

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

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Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 28 Apr 2021 21:48:45

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Name of Medication IPOAMIDOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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		IV
Start date (dd MMM yyyy)		23 NOV 2020
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 NOV 2020
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication POTASSIUM CHLORIDE SR

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 20

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify EVERY 2 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication POTASSIUM CHLORIDE SR
TABLET

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 40

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ROTIGOTINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	26 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication SALINE PERIPHERAL FLUSH

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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		IV
Start date (dd MMM yyyy)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication SODIUM CHLORIDE FLUSH

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	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		IV
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication VALSARTAN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 320

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ZINC SULFATE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ZOLPIDEM

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q6H

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication ASCORBIC ACID

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF COVID 19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 28 Apr 2021 21:48:45

Generated On: 10 Jun 2021 09:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 21:48:49

Generated On: 10 Jun 2021 09:32:46

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 NOV 2020	CT OF CHEST	Adverse Event	
16 NOV 2020	ECHOCARDIOGRAM	Adverse Event	
19 DEC 2020	XR CHEST	Adverse Event	
20 DEC 2020	CONVALESCENT PLASMA	Adverse Event	
19 NOV 2020	HYPERGLYCEMIA CORRECTION	Adverse Event	

US3722066

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:32:46

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

US3722066

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:32:46

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 ☐

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	18/NOV/2020 18:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	20/NOV/2020 16:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	25/NOV/2020 19:07
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	14/DEC/2020 15:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	16/FEB/2021 13:32
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	04/MAR/2021 22:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	09/MAR/2021 13:37
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	10/MAR/2021 10:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	11/MAR/2021 16:52
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (10)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	15/MAR/2021 11:01
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (11)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	07/APR/2021 10:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (12)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	08/APR/2021 09:46
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (13)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	13/APR/2021 14:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (14)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	16/APR/2021 09:15
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (15)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000007
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	15
Date of submission (Pre-filled from custom function)	22/APR/2021 11:17
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/DEC/2020 15:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/JAN/2021 14:14
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/FEB/2021 13:39
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

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:48:50

Generated On: 10 Jun 2021 09:32:46

SAEID	USA-US083-2020-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	04/MAR/2021 22:10
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

US3722066 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722066

Form: Participant Creation

Generated On: 10 Jun 2021 09:32:46

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'US3722066'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:54:23

US3722066

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Amy Ford (b) (4)	03 Aug 2020 21:46:50

US3722066

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '03 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:54:24

US3722066

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Clinic (Clinic)'	Amy Ford (b) (4)	03 Aug 2020 21:46:50

US3722066

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'SCRN'	System	03 Aug 2020 21:46:50

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:54:25

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
Query 'Per CDM: Please not Age (67) does not match with Age Derived (68). Please review and update accordingly.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:18:57
User opened query 'Per CDM: Please not Age (67) does not match with Age Derived (68). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:55:11
User entered '67'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'YEARS'	System	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '68'	System	03 Aug 2020 21:47:21

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Male (M)'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'I'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:47:06

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '3 Aug 2020'	Amy Ford (b) (4)	03 Aug 2020 21:47:21

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Aug 2020'	System	03 Aug 2020 21:47:21

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2020'	System	03 Aug 2020 21:47:21

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:12
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:35:26
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:35:22
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 07:21:13
User entered 'Amendment 5 (5)'	Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:47:21

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Amy Ford (b) (4)	03 Aug 2020 21:47:21

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Amy Ford (b) (4)	03 Aug 2020 21:47:21

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Amy Ford (b) (4)	03 Aug 2020 21:47:21

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:47:21

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:54:24

US3722066

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'I'	System	03 Aug 2020 21:47:28

US3722066

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Amy Ford (b) (4)	03 Aug 2020 21:47:28

US3722066

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:32:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:00:12

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:02:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:02:20
Data point term sent to Coder	System	06 Aug 2020 13:01:08
User entered 'Hypertension'	Kayla Peay (b) (4)	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 2005'	Kayla Peay (b) (4)	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 2005'	System	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2005'	System	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:00:38

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 20:39:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:39:02
Data point term sent to Coder	System	06 Aug 2020 13:01:09
User entered 'Hypercholesterol'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 1990'	Kayla Peay (b) (4)	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 1990'	System	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1990'	System	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:01:07

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:03:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:03:07
Data point term sent to Coder	System	06 Aug 2020 13:02:10
User entered 'Restless leg syndrome'	Kayla Peay (b) (4)	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 2015'	Kayla Peay (b) (4)	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 2015'	System	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2015'	System	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:01:29

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
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)	06 Aug 2020 13:03:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:03:07
Data point term sent to Coder	System	06 Aug 2020 13:02:10
User entered 'Hypothyroidism'	Kayla Peay (b) (4)	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 1990'	Kayla Peay (b) (4)	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 1990'	System	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1990'	System	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:01:50

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 13:03:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:03:07
Data point term sent to Coder	System	06 Aug 2020 13:02:10
User entered 'GERD'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN Jul 1990'	Kayla Peay (b) (4)	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jul 1990'	System	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1990'	System	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:02:10

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:04:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:04:10
Data point term sent to Coder	System	06 Aug 2020 13:03:11
User entered 'Asthma'	Kayla Peay (b) (4)	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 1956'	Kayla Peay (b) (4)	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 1956'	System	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1956'	System	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:02:29

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:04:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:04:10
Data point term sent to Coder	System	06 Aug 2020 13:03:10
User entered 'Seasonal allergies'	Kayla Peay (b) (4)	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 1956'	Kayla Peay (b) (4)	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 1956'	System	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1956'	System	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:02:56

US3722066

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Generalised osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:46:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:46:58
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate.	(b) (4), (b) (6)	25 Sep 2020 18:54:33
' (Site from DM).		
Data point term sent to Coder	System	25 Sep 2020 13:25:13
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate.	Amy Ford (b) (4)	25 Sep 2020 13:24:44
' answered with 'updated' (Site from DM).		
Coding entries removed.	Amy Ford (b) (4)	25 Sep 2020 13:24:39
User entered 'OSTEOARTHRITIS in right knee and hip, bilateral thumbs and shoulders' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate.	Amy Ford (b) (4)	25 Sep 2020 13:24:39
' (Site from DM).	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	(b) (4), (b) (6)	25 Sep 2020 11:57:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4), (b) (6)	
Data point term sent to Coder	Coder Import (b) (4)	06 Aug 2020 13:05:18
User entered 'Osteoarthritis'	(b) (4)	
	Coder Import (b) (4)	06 Aug 2020 13:05:18
	(b) (4)	
	System	06 Aug 2020 13:04:11
	Kayla Peay (b) (4)	06 Aug 2020 13:03:46
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 1990'	Kayla Peay (b) (4)	06 Aug 2020 13:03:46

US3722066

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:03:46

US3722066

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:03:46

US3722066

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:03:46

US3722066

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:03:46

US3722066

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 1990'	System	06 Aug 2020 13:03:46

US3722066

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1990'	System	06 Aug 2020 13:03:46

US3722066

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:03:46

US3722066

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	06 Aug 2020 13:03:46

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:19:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:19:12
Data point term sent to Coder	System	06 Aug 2020 13:05:14
User entered 'Tore rotator cuff left shoulder'	Kayla Peay (b) (4)	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 1972'	Kayla Peay (b) (4)	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Kayla Peay (b) (4)	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 2017'	Kayla Peay (b) (4)	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 1972'	System	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1972'	System	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 2017'	System	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2017'	System	06 Aug 2020 13:04:27

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:19:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:19:13
Data point term sent to Coder	System	06 Aug 2020 13:05:14
User entered 'Tore rotator cuff right shoulder'	Kayla Peay (b) (4)	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 1972'	Kayla Peay (b) (4)	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Kayla Peay (b) (4)	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 2015'	Kayla Peay (b) (4)	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 1972'	System	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1972'	System	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 2015'	System	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2015'	System	06 Aug 2020 13:05:10

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:07:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:07:17
Data point term sent to Coder	System	06 Aug 2020 13:06:15
User entered 'Abdominal hernia'	Kayla Peay (b) (4)	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 2006'	Kayla Peay (b) (4)	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Kayla Peay (b) (4)	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 2006'	Kayla Peay (b) (4)	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 2006'	System	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2006'	System	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 2006'	System	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2006'	System	06 Aug 2020 13:05:40

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Sep 2020 21:03:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 21:03:44
Data point term sent to Coder	System	24 Sep 2020 21:03:00
User entered 'vasectomy'	Kayla Peay (b) (4) (b) (4)	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'un UNK 1988'	Kayla Peay (b) (4)	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Kayla Peay (b) (4)	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 1988'	System	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1988'	System	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
Query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 22:13:27
User opened query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 12:37:25
User entered empty.	System	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	24 Sep 2020 21:02:56

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:30:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:30:40
Data point term sent to Coder	System	21 Oct 2020 17:29:43
User entered 'IRON DEFICIENCY ANEMIA'	Amy Ford (b) (4)	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'UN UNK 1995'	Amy Ford (b) (4)	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Amy Ford (b) (4)	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Amy Ford (b) (4)	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 1995'	System	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '1995'	System	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	21 Oct 2020 17:29:42

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Renal and urinary disorders, HLT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Jan 2021 13:46:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 13:46:03
Data point term sent to Coder	System	20 Jan 2021 13:45:10
User entered 'chronic kidney disease stage 3'	Marlee Smith (b) (4)	20 Jan 2021 13:44:24
	(b) (4)	

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'un UNK 2010'	Marlee Smith (b) (4)	20 Jan 2021 13:44:24

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Marlee Smith (b) (4)	20 Jan 2021 13:44:24

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Marlee Smith (b) (4)	20 Jan 2021 13:44:24

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Marlee Smith (b) (4)	20 Jan 2021 13:44:24

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Marlee Smith (b) (4)	20 Jan 2021 13:44:24

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 2010'	System	20 Jan 2021 13:44:24

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2010'	System	20 Jan 2021 13:44:24

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	20 Jan 2021 13:44:24

US3722066

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	20 Jan 2021 13:44:24

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 13:46:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 13:46:05
Data point term sent to Coder	System	20 Jan 2021 13:45:10
User entered 'obstructive sleep apnea'	Marlee Smith (b) (4)	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '05 May 2014'	Marlee Smith (b) (4)	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Marlee Smith (b) (4)	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Marlee Smith (b) (4)	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Marlee Smith (b) (4)	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Marlee Smith (b) (4)	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'May 2014'	System	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2014'	System	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	20 Jan 2021 13:44:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 03:43:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:30:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:30:57
Data point term sent to Coder	System	09 Mar 2021 15:29:57
User entered 'Rhinorrhea'	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'un UNK 2019'	Marlee Smith (b) (4)	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '0'	Marlee Smith (b) (4)	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Yes (Y)'	Marlee Smith (b) (4)	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	Marlee Smith (b) (4)	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '0'	Marlee Smith (b) (4)	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Jan 2019'	System	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '2019'	System	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:43
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	System	09 Mar 2021 15:29:43

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:06:53

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '3 Aug 2020'	Kayla Peay (b) (4)	06 Aug 2020 13:06:53

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '17:11'	Kayla Peay (b) (4)	06 Aug 2020 13:06:53

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '3 Aug 2020 17:11'	System	06 Aug 2020 13:06:53

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '167' cm	(b) (4) Kayla Peay (b) (4)	06 Aug 2020 13:06:53
DataPoint set to visible.	(b) (4) System	03 Aug 2020 21:47:28

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '88.9' kg	(b) (4) Kayla Peay (b) (4)	06 Aug 2020 13:06:53
DataPoint set to visible.	(b) (4) System	03 Aug 2020 21:47:28

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
Amendment Manager: User entered '31.87637'	System	16 Sep 2020 23:41:47
User entered '31.9'	System	06 Aug 2020 13:06:53
DataPoint set to visible.	System	03 Aug 2020 21:47:28

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'kg/m2'	System	06 Aug 2020 13:06:53
DataPoint set to visible.	System	03 Aug 2020 21:47:28

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:29
User entered '98.6' F	Kayla Peay (b) (4)	06 Aug 2020 13:06:53
	(b) (4)	

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:29
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	06 Aug 2020 13:06:53
	(b) (4)	

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:06:53

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:29
User entered '77'	Kayla Peay (b) (4)	06 Aug 2020 13:06:53
	(b) (4)	

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'bpm'	System	06 Aug 2020 13:06:53

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:29
User entered '16'	Kayla Peay (b) (4)	06 Aug 2020 13:06:53
	(b) (4)	

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'breaths/min'	System	06 Aug 2020 13:06:53

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:29
User entered '130'	Kayla Peay (b) (4)	06 Aug 2020 13:06:53
	(b) (4)	

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'mmHg'	System	06 Aug 2020 13:06:53

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:29
User entered '81'	Kayla Peay (b) (4)	06 Aug 2020 13:06:53
	(b) (4)	

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'mmHg'	System	06 Aug 2020 13:06:53

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17

US3722066

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17

US3722066

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:07:05

US3722066

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
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 14:12:33
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 16:19:29
User entered '3 Aug 2020'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:05

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	(b) (4) Amy Ford (b) (4) (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Amy Ford (b) (4)	03 Aug 2020 21:48:00

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'I'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '0'	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	Amy Ford (b) (4)	03 Aug 2020 21:48:00

US3722066

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Amy Ford (b) (4)	03 Aug 2020 21:48:35

US3722066

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '3 Aug 2020'	Amy Ford (b) (4)	03 Aug 2020 21:48:35

US3722066

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Clinic (Clinic)'	Amy Ford (b) (4)	03 Aug 2020 21:48:35

US3722066

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'VISIT1'	System	03 Aug 2020 21:48:35

US3722066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '03 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:24:10

US3722066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:50:15
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:50:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 21:24:10
User entered '184495' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:24:10

US3722066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:24:10

US3722066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:46

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Amy Ford (b) (4)	03 Aug 2020 21:48:51

US3722066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:46

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:51

US3722066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:51

US3722066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:46

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:51

US3722066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'No (N)'	Amy Ford (b) (4)	03 Aug 2020 21:48:51

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:38
User entered '167' cm reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kayla Peay (b) (4)	08 Sep 2020 14:41:38
User entered '196' lb reason for change: Data Entry Error	(b) (4) Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	(b) (4) Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:38
User entered '167' cm reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kayla Peay (b) (4)	08 Sep 2020 14:41:38
User entered '196' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered 'No (N)'	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '3 Aug 2020' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '17:09' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered '3 Aug 2020 17:09'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '98.6' F reason for change: Data Entry Error	(b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '77' reason for change: Data Entry Error	(b) (4) Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	(b) (4) Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'bpm'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '16' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'breaths/min'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '130' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'mmHg'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '81' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'mmHg'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:38
User entered '167' cm reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:38
User entered '196' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 15:18:23
User entered 'No (N)'	Kayla Peay (b) (4)	06 Aug 2020 13:07:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '3 Aug 2020' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 12:46:21
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).		11 Aug 2020 15:18:23
User entered '18:14' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered '3 Aug 2020 18:14'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '97.9' F reason for change: Data Entry Error	(b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '72' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'bpm'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '16' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'breaths/min'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '128' reason for change: Data Entry Error	(b) (4) Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	(b) (4) Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:07:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'mmHg'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '81' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:18:23
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'mmHg'	System	11 Aug 2020 15:18:23
User entered empty.	System	06 Aug 2020 13:07:21

US3722066

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 14:41:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:16:34
User entered 'No (N)'	Kayla Peay (b) (4)	06 Aug 2020 13:07:24

US3722066

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 14:41:45
User entered '3 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:16:34
User entered empty.	Kayla Peay (b) (4)	06 Aug 2020 13:07:24

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Amy Ford (b) (4)	03 Aug 2020 21:49:25

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered empty.	Amy Ford (b) (4)	03 Aug 2020 21:49:25

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered empty.	Amy Ford (b) (4)	03 Aug 2020 21:49:25

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 21:49:25

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '3 Aug 2020'	Amy Ford (b) (4)	03 Aug 2020 21:49:25

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '17:44'	Amy Ford (b) (4)	03 Aug 2020 21:49:25

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered '3 Aug 2020 17:44'	System	03 Aug 2020 21:49:25

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Left Arm (LEFT ARM)'	Amy Ford (b) (4)	03 Aug 2020 21:49:25

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'ONCE'	System	03 Aug 2020 21:49:25

US3722066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 21:49:25

US3722066

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:07:47

US3722066

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '3 Aug 2020'	Kayla Peay (b) (4)	06 Aug 2020 13:07:47

US3722066

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '17:24'	Kayla Peay (b) (4)	06 Aug 2020 13:07:47

US3722066

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered '3 Aug 2020 17:24'	System	06 Aug 2020 13:07:47

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '3 Aug 2020'	Kayla Peay (b) (4)	06 Aug 2020 13:08:01

US3722066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:01

US3722066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:08:01

US3722066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '17:18'	Kayla Peay (b) (4)	06 Aug 2020 13:08:01

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:46

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered '3 Aug 2020 17:18'	System	06 Aug 2020 13:08:01

US3722066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:08:01

US3722066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:08:01

US3722066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '17:18'	Kayla Peay (b) (4)	06 Aug 2020 13:08:01

US3722066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:46

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered '3 Aug 2020 17:18'	System	06 Aug 2020 13:08:01

US3722066

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	06 Aug 2020 13:08:04

US3722066

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'I'	System	06 Aug 2020 13:08:04

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874' User entered 'Yes (Y)'	System	03 Aug 2020 22:17:06
	System	03 Aug 2020 22:17:06

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874' User entered '97.9'	System	03 Aug 2020 22:17:06
	System	03 Aug 2020 22:17:06

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874'	System	03 Aug 2020 22:17:06
User entered 'Yes (Y)'	System	03 Aug 2020 22:17:06

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874' User entered '0'	System	03 Aug 2020 22:17:06
	System	03 Aug 2020 22:17:06

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:56:20
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Amy Ford (b) (4)	17 Aug 2020 16:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:16:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874'	(b) (4)	
User entered '1'	System	03 Aug 2020 22:17:06

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:17:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92b26b3d-c534-4d14-a1cf-85a0edd7c874' User entered '03 Aug 2020 18:17'	System	03 Aug 2020 22:17:06
	System	03 Aug 2020 22:17:06

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Aug 2020 18:04'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Aug 2020 20:34'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	System	04 Aug 2020 01:36:58
User entered 'Yes (Y)'	System	04 Aug 2020 01:36:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6' User entered '98.2'	System	04 Aug 2020 01:36:58
	System	04 Aug 2020 01:36:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	System	04 Aug 2020 01:36:58
User entered 'Yes (Y)'	System	04 Aug 2020 01:36:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6' User entered '0'	System	04 Aug 2020 01:36:58
	System	04 Aug 2020 01:36:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:56:31
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Amy Ford (b) (4)	17 Aug 2020 16:05:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	(b) (4)	
User entered '1'	System	04 Aug 2020 01:36:58
	System	04 Aug 2020 01:36:58
	System	04 Aug 2020 01:36:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:36:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b4167d8c-ae99-4536-b883-68203d0694b6'	System	04 Aug 2020 01:36:58
User entered '03 Aug 2020 21:36'	System	04 Aug 2020 01:36:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Aug 2020 21:29'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 2'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148' User entered 'Yes (Y)'	System	04 Aug 2020 16:03:31
	System	04 Aug 2020 16:03:31

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148' User entered '98.6'	System	04 Aug 2020 16:03:31
	System	04 Aug 2020 16:03:31

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148'	System	04 Aug 2020 16:03:31
User entered 'Yes (Y)'	System	04 Aug 2020 16:03:31

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148' User entered '0'	System	04 Aug 2020 16:03:31
	System	04 Aug 2020 16:03:31

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:56:45
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148' User entered '1'	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:05:26
	System	04 Aug 2020 16:03:31
	System	04 Aug 2020 16:03:31
	System	04 Aug 2020 16:03:31

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9e770ae2-47b7-4bc6-96cd-4d769f746148' User entered '04 Aug 2020 12:03'	System	04 Aug 2020 16:03:31
	System	04 Aug 2020 16:03:31

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 3'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6' User entered 'Yes (Y)'	System	05 Aug 2020 16:07:34
	System	05 Aug 2020 16:07:34

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6' User entered '98.2'	System	05 Aug 2020 16:07:34
	System	05 Aug 2020 16:07:34

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6'	System	05 Aug 2020 16:07:34
User entered 'Yes (Y)'	System	05 Aug 2020 16:07:34

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6' User entered '0'	System	05 Aug 2020 16:07:34
	System	05 Aug 2020 16:07:34

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:57:02
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6' User entered '1'	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:05:35
	System	05 Aug 2020 16:07:34
	System	05 Aug 2020 16:07:34
	System	05 Aug 2020 16:07:34

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8f830f44-51bc-4509-a8f6-2b81f64770f6' User entered '05 Aug 2020 12:07'	System	05 Aug 2020 16:07:34
	System	05 Aug 2020 16:07:34

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 4'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered 'Yes (Y)'	System	06 Aug 2020 16:03:17

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295' User entered '98.3'	System	06 Aug 2020 16:03:17
	System	06 Aug 2020 16:03:17

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered 'Yes (Y)'	System	06 Aug 2020 16:03:17

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered '0'	System	06 Aug 2020 16:03:17

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:57:13
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	Amy Ford (b) (4)	17 Aug 2020 16:05:45
User entered '1'	(b) (4)	
	System	06 Aug 2020 16:03:17
	System	06 Aug 2020 16:03:17
	System	06 Aug 2020 16:03:17

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5b8b643f-9b2a-4191-9397-031d62d5a295'	System	06 Aug 2020 16:03:17
User entered '06 Aug 2020 12:03'	System	06 Aug 2020 16:03:17

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 5'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8'	System	07 Aug 2020 16:14:58
User entered 'Yes (Y)'	System	07 Aug 2020 16:14:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8' User entered '98.2'	System	07 Aug 2020 16:14:58
	System	07 Aug 2020 16:14:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8'	System	07 Aug 2020 16:14:58
User entered 'Yes (Y)'	System	07 Aug 2020 16:14:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8' User entered '0'	System	07 Aug 2020 16:14:58
	System	07 Aug 2020 16:14:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:57:24
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Amy Ford (b) (4)	17 Aug 2020 16:05:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8'	(b) (4)	
User entered '1'	System	07 Aug 2020 16:14:58
	System	07 Aug 2020 16:14:58
	System	07 Aug 2020 16:14:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:14:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8cff255c-b239-4a31-971b-2e74944539e8' User entered '07 Aug 2020 12:14'	System	07 Aug 2020 16:14:58
	System	07 Aug 2020 16:14:58

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 6'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4' User entered 'Yes (Y)'	System	08 Aug 2020 16:42:37
	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4' User entered '97.5'	System	08 Aug 2020 16:42:37
	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4' User entered 'Yes (Y)'	System	08 Aug 2020 16:42:37
	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4' User entered '0'	System	08 Aug 2020 16:42:37
	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:57:50
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Amy Ford (b) (4)	17 Aug 2020 16:06:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4'	(b) (4)	
User entered '1'	System	08 Aug 2020 16:42:37
	System	08 Aug 2020 16:42:37
	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '75f582e2-2e40-41bc-a615-7bdac1b365d4' User entered '08 Aug 2020 12:42'	System	08 Aug 2020 16:42:37
	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 7'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b' User entered 'Yes (Y)'	System	09 Aug 2020 16:02:41
	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b' User entered '97.7'	System	09 Aug 2020 16:02:41
	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b' User entered 'Yes (Y)'	System	09 Aug 2020 16:02:41
	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b' User entered '0'	System	09 Aug 2020 16:02:41
	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:58:05
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b'	Amy Ford (b) (4)	17 Aug 2020 16:06:16
User entered '1'	(b) (4)	
	System	09 Aug 2020 16:02:41
	System	09 Aug 2020 16:02:41
	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:37', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c3dba537-58df-4c19-a406-f374c63d3f8b'	System	09 Aug 2020 16:02:41
User entered '09 Aug 2020 12:02'	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	08 Aug 2020 16:42:37
User entered 'Day 8'	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:13:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53'	System	10 Aug 2020 16:14:07
User entered 'Yes (Y)'	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:13:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53' User entered '97.9'	System	10 Aug 2020 16:14:07
	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:13:59', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53'	System	10 Aug 2020 16:14:07
User entered 'Yes (Y)'	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53' User entered '0'	System	10 Aug 2020 16:14:07
	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:58:25
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53' User entered '1'	Amy Ford (b) (4) (b) (4)	17 Aug 2020 16:06:27
	System	10 Aug 2020 16:14:07
	System	10 Aug 2020 16:14:07
	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '38ea95c0-d1b4-41f6-bfa5-da8327303d53'	System	10 Aug 2020 16:14:07
User entered '10 Aug 2020 12:14'	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Query 'Per CDM: Timepoint Day 9 is not completed. Please update applicable fields as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 10:09:38
User opened query 'Per CDM: Timepoint Day 9 is not completed. Please update applicable fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 14:01:05
Data entry locked.	System	09 Aug 2020 16:02:41
User entered 'Day 9'	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	10 Aug 2020 16:14:07
User entered 'Day 10'	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21' User entered 'Yes (Y)'	System	12 Aug 2020 17:01:51
	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21' User entered '98.5'	System	12 Aug 2020 17:01:51
	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21'	System	12 Aug 2020 17:01:51
User entered 'Yes (Y)'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21' User entered '0'	System	12 Aug 2020 17:01:51
	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 06:38:49
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:19:31
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Aug 2020 17:01:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21'	System	12 Aug 2020 17:01:51
User entered '1'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '3f881402-fca9-4df5-a588-fb81a05b7b21'	System	12 Aug 2020 17:01:51
User entered '12 Aug 2020 13:01'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	12 Aug 2020 17:01:51
User entered 'Day 11'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce' User entered 'Yes (Y)'	System	13 Aug 2020 16:32:22
	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce' User entered '98.3'	System	13 Aug 2020 16:32:22
	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce' User entered 'Yes (Y)'	System	13 Aug 2020 16:32:22
	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce' User entered '0'	System	13 Aug 2020 16:32:22
	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 12:11:38
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:19:38
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Aug 2020 16:32:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce'	System	13 Aug 2020 16:32:22
User entered '1'	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fedd1a6e-7783-4059-8930-842e9f40fcce' User entered '13 Aug 2020 12:32'	System	13 Aug 2020 16:32:22
	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	12 Aug 2020 17:01:51
User entered 'Day 12'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246' User entered 'Yes (Y)'	System	14 Aug 2020 16:14:00
	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246' User entered '98.0'	System	14 Aug 2020 16:14:00
	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:54', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246'	System	14 Aug 2020 16:14:00
User entered 'Yes (Y)'	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246' User entered '0'	System	14 Aug 2020 16:14:00
	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 13:18:48
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:19:45
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Aug 2020 16:14:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246'	System	14 Aug 2020 16:14:00
User entered '1'	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:13:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd49650dd-79f3-4116-b79b-0f8354283246'	System	14 Aug 2020 16:14:00
User entered '14 Aug 2020 12:13'	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	13 Aug 2020 16:32:22
User entered 'Day 13'	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac' User entered 'Yes (Y)'	System	15 Aug 2020 16:05:16
	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac' User entered '98.3'	System	15 Aug 2020 16:05:16
	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac'	System	15 Aug 2020 16:05:16
User entered 'Yes (Y)'	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac' User entered '0'	System	15 Aug 2020 16:05:16
	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 13:19:09
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:19:52
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Aug 2020 16:05:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac'	System	15 Aug 2020 16:05:16
User entered '1'	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c22b8aac-7b95-41c6-936d-a09bedcb48ac'	System	15 Aug 2020 16:05:16
User entered '15 Aug 2020 12:05'	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	14 Aug 2020 16:14:00
User entered 'Day 14'	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:04:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d' User entered 'Yes (Y)'	System	16 Aug 2020 16:05:23
	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:04:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d' User entered '96.8'	System	16 Aug 2020 16:05:23
	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:04:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d' User entered 'Yes (Y)'	System	16 Aug 2020 16:05:23
	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d' User entered '0'	System	16 Aug 2020 16:05:23
	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 13:19:33
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:20:01
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Aug 2020 16:05:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d'	System	16 Aug 2020 16:05:23
User entered '1'	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '18ea5194-3ecc-4a06-8d5c-4cece752733d' User entered '16 Aug 2020 12:05'	System	16 Aug 2020 16:05:23
	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	15 Aug 2020 16:05:16
User entered 'Day 15'	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:45:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd' User entered 'Yes (Y)'	System	17 Aug 2020 16:46:44
	System	17 Aug 2020 16:46:44

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd' User entered '98.0'	System	17 Aug 2020 16:46:44
	System	17 Aug 2020 16:46:44

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd'	System	17 Aug 2020 16:46:44
User entered 'Yes (Y)'	System	17 Aug 2020 16:46:44

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd' User entered '0'	System	17 Aug 2020 16:46:44
	System	17 Aug 2020 16:46:44

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 13:19:52
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted' (Site from System).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:20:10
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Aug 2020 16:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd'	System	17 Aug 2020 16:46:44
User entered '1'	System	17 Aug 2020 16:46:44

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ab74b292-3d58-4e91-8a04-1216b1d299fd' User entered '17 Aug 2020 12:46'	System	17 Aug 2020 16:46:44
	System	17 Aug 2020 16:46:44

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	16 Aug 2020 16:05:23
User entered 'Day 16'	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0b44a613-be92-4f7e-9367-2f133eb1d3c9' User entered 'Yes (Y)'	System	18 Aug 2020 17:17:47
	System	18 Aug 2020 17:17:47

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0b44a613-be92-4f7e-9367-2f133eb1d3c9' User entered '98.7'	System	18 Aug 2020 17:17:47
	System	18 Aug 2020 17:17:47

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 10 Jun 2021 09:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0b44a613-be92-4f7e-9367-2f133eb1d3c9'	System	18 Aug 2020 17:17:47
User entered 'No (N)'	System	18 Aug 2020 17:17:47

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0b44a613-be92-4f7e-9367-2f133eb1d3c9' User entered '18 Aug 2020 12:17'	System	18 Aug 2020 17:17:47
	System	18 Aug 2020 17:17:47

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:17:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040' User entered 'None (1)'	System	03 Aug 2020 22:18:29
	System	03 Aug 2020 22:18:29

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040' User entered 'No (N)'	System	03 Aug 2020 22:18:29
	System	03 Aug 2020 22:18:29

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040' User entered 'No (N)'	System	03 Aug 2020 22:18:29
	System	03 Aug 2020 22:18:29

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040' User entered 'None (1)'	System	03 Aug 2020 22:18:29
	System	03 Aug 2020 22:18:29

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cd096edc-3d4f-430c-93d4-2a4e36a32040' User entered '03 Aug 2020 18:18'	System	03 Aug 2020 22:18:29
	System	03 Aug 2020 22:18:29

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Aug 2020 18:04'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Aug 2020 20:34'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered 'None (1)'	System	04 Aug 2020 01:37:26

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:11', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered 'No (N)'	System	04 Aug 2020 01:37:26

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered 'No (N)'	System	04 Aug 2020 01:37:26

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered 'None (1)'	System	04 Aug 2020 01:37:26

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bc879cd5-fbbe-48f8-b78c-67e1b1903ccc'	System	04 Aug 2020 01:37:26
User entered '03 Aug 2020 21:37'	System	04 Aug 2020 01:37:26

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Aug 2020 21:29'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 2'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80'	System	04 Aug 2020 16:03:49
User entered 'None (1)'	System	04 Aug 2020 16:03:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80' User entered 'No (N)'	System	04 Aug 2020 16:03:49
	System	04 Aug 2020 16:03:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80' User entered 'No (N)'	System	04 Aug 2020 16:03:49
	System	04 Aug 2020 16:03:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80'	System	04 Aug 2020 16:03:49
User entered 'None (1)'	System	04 Aug 2020 16:03:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2e4b71a3-ae00-4a93-8e04-3d76d484bb80' User entered '04 Aug 2020 12:03'	System	04 Aug 2020 16:03:49
	System	04 Aug 2020 16:03:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 3'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53'	System	05 Aug 2020 16:07:49
User entered 'None (1)'	System	05 Aug 2020 16:07:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53'	System	05 Aug 2020 16:07:49
User entered 'No (N)'	System	05 Aug 2020 16:07:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53'	System	05 Aug 2020 16:07:49
User entered 'No (N)'	System	05 Aug 2020 16:07:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53'	System	05 Aug 2020 16:07:49
User entered 'None (1)'	System	05 Aug 2020 16:07:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bb3ba382-dc81-4201-ba63-998ab626eb53' User entered '05 Aug 2020 12:07'	System	05 Aug 2020 16:07:49
	System	05 Aug 2020 16:07:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 4'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071' User entered 'None (1)'	System	06 Aug 2020 16:03:32
	System	06 Aug 2020 16:03:32

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071' User entered 'No (N)'	System	06 Aug 2020 16:03:32
	System	06 Aug 2020 16:03:32

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071' User entered 'No (N)'	System	06 Aug 2020 16:03:32
	System	06 Aug 2020 16:03:32

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071' User entered 'None (1)'	System	06 Aug 2020 16:03:32
	System	06 Aug 2020 16:03:32

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5923cd01-df17-41ea-8143-da453cc50071' User entered '06 Aug 2020 12:03'	System	06 Aug 2020 16:03:32
	System	06 Aug 2020 16:03:32

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 5'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554'	System	07 Aug 2020 16:15:12
User entered 'None (1)'	System	07 Aug 2020 16:15:12

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:03', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554'	System	07 Aug 2020 16:15:12
User entered 'No (N)'	System	07 Aug 2020 16:15:12

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554'	System	07 Aug 2020 16:15:12
User entered 'No (N)'	System	07 Aug 2020 16:15:12

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:07', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554' User entered 'None (1)'	System	07 Aug 2020 16:15:12
	System	07 Aug 2020 16:15:12

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bae7238b-a978-4306-bdac-58ea4eca1554' User entered '07 Aug 2020 12:15'	System	07 Aug 2020 16:15:12
	System	07 Aug 2020 16:15:12

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 6'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6'	System	08 Aug 2020 16:42:49
User entered 'None (1)'	System	08 Aug 2020 16:42:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6'	System	08 Aug 2020 16:42:49
User entered 'No (N)'	System	08 Aug 2020 16:42:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6'	System	08 Aug 2020 16:42:49
User entered 'No (N)'	System	08 Aug 2020 16:42:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6' User entered 'None (1)'	System	08 Aug 2020 16:42:49
	System	08 Aug 2020 16:42:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c2f3c5d4-d402-4b58-aba7-e4d21b455fd6' User entered '08 Aug 2020 12:42'	System	08 Aug 2020 16:42:49
	System	08 Aug 2020 16:42:49

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 7'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b' User entered 'None (1)'	System	09 Aug 2020 16:03:03
	System	09 Aug 2020 16:03:03

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b' User entered 'No (N)'	System	09 Aug 2020 16:03:03
	System	09 Aug 2020 16:03:03

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b' User entered 'No (N)'	System	09 Aug 2020 16:03:03
	System	09 Aug 2020 16:03:03

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:02:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b' User entered 'None (1)'	System	09 Aug 2020 16:03:03
	System	09 Aug 2020 16:03:03

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd1f7c46a-1ad1-4ddb-ad51-370fbfe84e5b' User entered '09 Aug 2020 12:03'	System	09 Aug 2020 16:03:03
	System	09 Aug 2020 16:03:03

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b' User entered 'None (0)'	System	03 Aug 2020 22:19:12
	System	03 Aug 2020 22:19:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:37', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b' User entered 'None (0)'	System	03 Aug 2020 22:19:12
	System	03 Aug 2020 22:19:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b' User entered 'None (0)'	System	03 Aug 2020 22:19:12
	System	03 Aug 2020 22:19:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b' User entered 'None (0)'	System	03 Aug 2020 22:19:12
	System	03 Aug 2020 22:19:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b' User entered 'None (0)'	System	03 Aug 2020 22:19:12
	System	03 Aug 2020 22:19:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:18:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b' User entered 'None (0)'	System	03 Aug 2020 22:19:12
	System	03 Aug 2020 22:19:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:19:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b' User entered 'No (N)'	System	03 Aug 2020 22:19:12
	System	03 Aug 2020 22:19:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T18:19:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7af66d27-476f-42c9-8113-c6af6bbe6b3b' User entered '03 Aug 2020 18:19'	System	03 Aug 2020 22:19:12
	System	03 Aug 2020 22:19:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Aug 2020 18:04'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Aug 2020 20:34'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e' User entered 'None (0)'	System	04 Aug 2020 01:38:01
	System	04 Aug 2020 01:38:01

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e' User entered 'None (0)'	System	04 Aug 2020 01:38:01
	System	04 Aug 2020 01:38:01

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e' User entered 'None (0)'	System	04 Aug 2020 01:38:01
	System	04 Aug 2020 01:38:01

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e' User entered 'None (0)'	System	04 Aug 2020 01:38:01
	System	04 Aug 2020 01:38:01

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e' User entered 'None (0)'	System	04 Aug 2020 01:38:01
	System	04 Aug 2020 01:38:01

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e' User entered 'None (0)'	System	04 Aug 2020 01:38:01
	System	04 Aug 2020 01:38:01

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e' User entered 'No (N)'	System	04 Aug 2020 01:38:01
	System	04 Aug 2020 01:38:01

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-03T21:37:59', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '13652d0b-62ad-483d-9e2b-b9501bc0899e' User entered '03 Aug 2020 21:37'	System	04 Aug 2020 01:38:01
	System	04 Aug 2020 01:38:01

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Aug 2020 21:29'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 2'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77' User entered 'None (0)'	System	04 Aug 2020 16:04:15
	System	04 Aug 2020 16:04:15

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77' User entered 'None (0)'	System	04 Aug 2020 16:04:15
	System	04 Aug 2020 16:04:15

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:57', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77' User entered 'None (0)'	System	04 Aug 2020 16:04:15
	System	04 Aug 2020 16:04:15

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:03:59', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77' User entered 'None (0)'	System	04 Aug 2020 16:04:15
	System	04 Aug 2020 16:04:15

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:04:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77' User entered 'None (0)'	System	04 Aug 2020 16:04:15
	System	04 Aug 2020 16:04:15

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:04:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77' User entered 'None (0)'	System	04 Aug 2020 16:04:15
	System	04 Aug 2020 16:04:15

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:04:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77' User entered 'No (N)'	System	04 Aug 2020 16:04:15
	System	04 Aug 2020 16:04:15

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-04T12:04:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '09b330d3-2489-4aa3-b452-527fd0b38a77'	System	04 Aug 2020 16:04:15
User entered '04 Aug 2020 12:04'	System	04 Aug 2020 16:04:15

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 3'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f' User entered 'None (0)'	System	05 Aug 2020 16:08:12
	System	05 Aug 2020 16:08:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f' User entered 'None (0)'	System	05 Aug 2020 16:08:12
	System	05 Aug 2020 16:08:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f' User entered 'None (0)'	System	05 Aug 2020 16:08:12
	System	05 Aug 2020 16:08:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:07:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f' User entered 'None (0)'	System	05 Aug 2020 16:08:12
	System	05 Aug 2020 16:08:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:08:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f' User entered 'None (0)'	System	05 Aug 2020 16:08:12
	System	05 Aug 2020 16:08:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:08:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f' User entered 'None (0)'	System	05 Aug 2020 16:08:12
	System	05 Aug 2020 16:08:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:08:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f' User entered 'No (N)'	System	05 Aug 2020 16:08:12
	System	05 Aug 2020 16:08:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-05T12:08:07', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2158af88-0a90-43d9-be41-74b08c03652f' User entered '05 Aug 2020 12:08'	System	05 Aug 2020 16:08:12
	System	05 Aug 2020 16:08:12

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 4'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d' User entered 'None (0)'	System	06 Aug 2020 16:03:52
	System	06 Aug 2020 16:03:52

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d' User entered 'None (0)'	System	06 Aug 2020 16:03:52
	System	06 Aug 2020 16:03:52

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d' User entered 'None (0)'	System	06 Aug 2020 16:03:52
	System	06 Aug 2020 16:03:52

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d' User entered 'None (0)'	System	06 Aug 2020 16:03:52
	System	06 Aug 2020 16:03:52

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d' User entered 'None (0)'	System	06 Aug 2020 16:03:52
	System	06 Aug 2020 16:03:52

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d' User entered 'None (0)'	System	06 Aug 2020 16:03:52
	System	06 Aug 2020 16:03:52

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d' User entered 'No (N)'	System	06 Aug 2020 16:03:52
	System	06 Aug 2020 16:03:52

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-06T12:03:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '62559a7c-917c-4917-b3e3-fcab1e17477d' User entered '06 Aug 2020 12:03'	System	06 Aug 2020 16:03:52
	System	06 Aug 2020 16:03:52

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 5'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:15', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef' User entered 'None (0)'	System	07 Aug 2020 16:15:34
	System	07 Aug 2020 16:15:34

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef' User entered 'None (0)'	System	07 Aug 2020 16:15:34
	System	07 Aug 2020 16:15:34

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef' User entered 'None (0)'	System	07 Aug 2020 16:15:34
	System	07 Aug 2020 16:15:34

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef' User entered 'None (0)'	System	07 Aug 2020 16:15:34
	System	07 Aug 2020 16:15:34

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef' User entered 'None (0)'	System	07 Aug 2020 16:15:34
	System	07 Aug 2020 16:15:34

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef' User entered 'None (0)'	System	07 Aug 2020 16:15:34
	System	07 Aug 2020 16:15:34

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef' User entered 'No (N)'	System	07 Aug 2020 16:15:34
	System	07 Aug 2020 16:15:34

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-07T12:15:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '92683bf3-e68d-4079-b67a-090e1a1e56ef' User entered '07 Aug 2020 12:15'	System	07 Aug 2020 16:15:34
	System	07 Aug 2020 16:15:34

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 6'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546' User entered 'None (0)'	System	08 Aug 2020 16:43:08
	System	08 Aug 2020 16:43:08

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546' User entered 'None (0)'	System	08 Aug 2020 16:43:08
	System	08 Aug 2020 16:43:08

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:54', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546' User entered 'None (0)'	System	08 Aug 2020 16:43:08
	System	08 Aug 2020 16:43:08

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546' User entered 'None (0)'	System	08 Aug 2020 16:43:08
	System	08 Aug 2020 16:43:08

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:42:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546' User entered 'None (0)'	System	08 Aug 2020 16:43:08
	System	08 Aug 2020 16:43:08

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:43:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546' User entered 'None (0)'	System	08 Aug 2020 16:43:08
	System	08 Aug 2020 16:43:08

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:43:03', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546'	System	08 Aug 2020 16:43:08
User entered 'No (N)'	System	08 Aug 2020 16:43:08

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-08T12:43:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a202ca-c543-4b69-a4cc-b1c6a4ea4546' User entered '08 Aug 2020 12:43'	System	08 Aug 2020 16:43:08
	System	08 Aug 2020 16:43:08

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 7'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21' User entered 'None (0)'	System	09 Aug 2020 16:03:24
	System	09 Aug 2020 16:03:24

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21' User entered 'None (0)'	System	09 Aug 2020 16:03:24
	System	09 Aug 2020 16:03:24

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21' User entered 'None (0)'	System	09 Aug 2020 16:03:24
	System	09 Aug 2020 16:03:24

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:11', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21' User entered 'None (0)'	System	09 Aug 2020 16:03:24
	System	09 Aug 2020 16:03:24

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21' User entered 'None (0)'	System	09 Aug 2020 16:03:24
	System	09 Aug 2020 16:03:24

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:15', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21' User entered 'None (0)'	System	09 Aug 2020 16:03:24
	System	09 Aug 2020 16:03:24

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21' User entered 'No (N)'	System	09 Aug 2020 16:03:24
	System	09 Aug 2020 16:03:24

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-09T12:03:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '23f35d81-ee52-40ea-8bdd-814e108d4d21' User entered '09 Aug 2020 12:03'	System	09 Aug 2020 16:03:24
	System	09 Aug 2020 16:03:24

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	08 Aug 2020 16:42:37
User entered 'Day 8'	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8b3f8e23-6d02-4737-bc1f-e43746fe6098'	System	10 Aug 2020 16:14:14
User entered 'No (N)'	System	10 Aug 2020 16:14:14

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-10T12:14:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '8b3f8e23-6d02-4737-bc1f-e43746fe6098'	System	10 Aug 2020 16:14:14
User entered '10 Aug 2020 12:14'	System	10 Aug 2020 16:14:14

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 16:42:37

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	09 Aug 2020 16:02:41
User entered 'Day 9'	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 16:02:41

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	10 Aug 2020 16:14:07
User entered 'Day 10'	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fc287c22-abbe-40b7-a74d-5c4fff485944'	System	12 Aug 2020 17:01:56
User entered 'No (N)'	System	12 Aug 2020 17:01:56

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-12T13:01:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'fc287c22-abbe-40b7-a74d-5c4fff485944'	System	12 Aug 2020 17:01:56
User entered '12 Aug 2020 13:01'	System	12 Aug 2020 17:01:56

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:14:07

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	12 Aug 2020 17:01:51
User entered 'Day 11'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bf984dc5-91b1-4b13-ad24-61ce2ba3bc37'	System	13 Aug 2020 16:32:29
User entered 'No (N)'	System	13 Aug 2020 16:32:29

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-13T12:32:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'bf984dc5-91b1-4b13-ad24-61ce2ba3bc37'	System	13 Aug 2020 16:32:29
User entered '13 Aug 2020 12:32'	System	13 Aug 2020 16:32:29

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	12 Aug 2020 17:01:51
User entered 'Day 12'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:14:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5d32548d-40f8-402f-8f05-32d67f77ff41' User entered 'No (N)'	System	14 Aug 2020 16:14:43
	System	14 Aug 2020 16:14:43

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-14T12:14:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5d32548d-40f8-402f-8f05-32d67f77ff41' User entered '14 Aug 2020 12:14'	System	14 Aug 2020 16:14:43
	System	14 Aug 2020 16:14:43

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:01:51

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	13 Aug 2020 16:32:22
User entered 'Day 13'	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '43d82bda-e765-4850-9cd4-f0d42ead2b95'	System	15 Aug 2020 16:05:22
User entered 'No (N)'	System	15 Aug 2020 16:05:22

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-15T12:05:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '43d82bda-e765-4850-9cd4-f0d42ead2b95'	System	15 Aug 2020 16:05:22
User entered '15 Aug 2020 12:05'	System	15 Aug 2020 16:05:22

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:32:22

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	14 Aug 2020 16:14:00
User entered 'Day 14'	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '74d59fdc-2d8d-4d39-aecb-1aba5a95980a' User entered 'No (N)'	System	16 Aug 2020 16:05:37
	System	16 Aug 2020 16:05:37

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-16T12:05:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '74d59fdc-2d8d-4d39-aecb-1aba5a95980a' User entered '16 Aug 2020 12:05'	System	16 Aug 2020 16:05:37
	System	16 Aug 2020 16:05:37

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:14:00

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	15 Aug 2020 16:05:16
User entered 'Day 15'	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd99264ae-57b6-4763-a8bf-bf27a22148ae' User entered 'No (N)'	System	17 Aug 2020 16:46:59
	System	17 Aug 2020 16:46:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-17T12:46:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd99264ae-57b6-4763-a8bf-bf27a22148ae' User entered '17 Aug 2020 12:46'	System	17 Aug 2020 16:46:59
	System	17 Aug 2020 16:46:59

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 16:05:16

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	16 Aug 2020 16:05:23
User entered 'Day 16'	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '681b04b1-67c3-4b00-afc6-db41184c7326' User entered 'No (N)'	System	18 Aug 2020 17:17:54
	System	18 Aug 2020 17:17:54

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-18T12:17:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '681b04b1-67c3-4b00-afc6-db41184c7326' User entered '18 Aug 2020 12:17'	System	18 Aug 2020 17:17:54
	System	18 Aug 2020 17:17:54

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 16:05:23

US3722066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 16:05:23

US3722066

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	11 Aug 2020 01:13:30

US3722066

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '10 Aug 2020'	Kayla Peay (b) (4)	11 Aug 2020 01:13:30

US3722066

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	11 Aug 2020 01:13:30

US3722066

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered empty.	Kayla Peay (b) (4)	11 Aug 2020 01:13:30

US3722066

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	11 Aug 2020 01:13:42

US3722066

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'I'	System	11 Aug 2020 01:13:42

US3722066

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	26 Aug 2020 01:35:15

US3722066

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '18 Aug 2020'	Kayla Peay (b) (4)	26 Aug 2020 01:35:15

US3722066

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kayla Peay (b) (4) (b) (4)	26 Aug 2020 01:35:15

US3722066

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered empty.	Kayla Peay (b) (4)	26 Aug 2020 01:35:15

US3722066

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	26 Aug 2020 01:35:20

US3722066

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:38:24
User entered 'I'	System	26 Aug 2020 01:35:20

US3722066

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	27 Aug 2020 12:59:33

US3722066

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '26 Aug 2020'	Kayla Peay (b) (4)	27 Aug 2020 12:59:33

US3722066

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	27 Aug 2020 12:59:33

US3722066

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered empty.	Kayla Peay (b) (4)	27 Aug 2020 12:59:33

US3722066

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	27 Aug 2020 12:59:25

US3722066

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'I'	System	27 Aug 2020 12:59:25

US3722066

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Sara Poff (b) (4)	28 Aug 2020 16:19:29

US3722066

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Aug 2020 19:23:44
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Per protocol subject is in window' (Site from System).	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:19:44
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	28 Aug 2020 16:19:29
User entered '28 Aug 2020'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 16:19:29

US3722066

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	28 Aug 2020 16:19:29

US3722066

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'VISIT2'	System	28 Aug 2020 16:19:29

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '10:35'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered '28 Aug 2020 10:35'	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '98.7' F	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '71'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'bpm'	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '19'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'breaths/min'	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '144'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'mmHg'	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '83'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'mmHg'	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		28 Aug 2020 18:04:23
User entered '12:21' reason for change: Data Entry Error	Kayla Peay (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered '28 Aug 2020 12:21'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		28 Aug 2020 18:04:23
User entered '97.5' F reason for change: Data Entry Error	Kayla Peay (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		28 Aug 2020 18:04:23
User entered '76' reason for change: Data Entry Error	Kayla Peay (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 15:28:30
	(b) (4)	

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'bpm'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		28 Aug 2020 18:04:23
User entered '18' reason for change: Data Entry Error	Kayla Peay (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'breaths/min'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		28 Aug 2020 18:04:23
User entered '129' reason for change: Data Entry Error	Kayla Peay (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 15:28:30
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'mmHg'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 18:04:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		28 Aug 2020 18:04:23
User entered '89' reason for change: Data Entry Error	Kayla Peay (b) (4)	28 Aug 2020 18:04:23
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 15:28:30
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 15:28:30
	(b) (4)	

US3722066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'mmHg'	System	28 Aug 2020 18:04:23
User entered empty.	System	28 Aug 2020 15:28:30

US3722066

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 15:28:39

US3722066

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 15:28:39

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Sara Poff (b) (4)	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered empty.	Sara Poff (b) (4)	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered empty.	Sara Poff (b) (4)	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '28 Aug 2020'	Sara Poff (b) (4)	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '11:51'	Sara Poff (b) (4)	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered '28 Aug 2020 11:51'	System	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'ONCE'	System	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 16:20:07

US3722066

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 18:03:50

US3722066

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 18:03:50

US3722066

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '11:25'	Kayla Peay (b) (4)	28 Aug 2020 18:03:50

US3722066

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered '28 Aug 2020 11:25'	System	28 Aug 2020 18:03:50

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 15:28:59

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:59

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 15:28:59

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '10:57'	Kayla Peay (b) (4)	28 Aug 2020 15:28:59

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered '28 Aug 2020 10:57'	System	28 Aug 2020 15:28:59

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 15:28:59

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 15:28:59

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '10:57'	Kayla Peay (b) (4)	28 Aug 2020 15:28:59

US3722066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered '28 Aug 2020 10:57'	System	28 Aug 2020 15:28:59

US3722066

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Sara Poff (b) (4)	28 Aug 2020 16:20:15

US3722066

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'I'	System	28 Aug 2020 16:20:15

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:13', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c80e38cf-bbc4-42dc-903d-a1e99b18fd75'	System	28 Aug 2020 16:21:39
User entered 'Yes (Y)'	System	28 Aug 2020 16:21:39

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c80e38cf-bbc4-42dc-903d-a1e99b18fd75' User entered '97.5'	System	28 Aug 2020 16:21:39
	System	28 Aug 2020 16:21:39

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c80e38cf-bbc4-42dc-903d-a1e99b18fd75'	System	28 Aug 2020 16:21:39
User entered 'No (N)'	System	28 Aug 2020 16:21:39

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c80e38cf-bbc4-42dc-903d-a1e99b18fd75'	System	28 Aug 2020 16:21:39
User entered '28 Aug 2020 12:21'	System	28 Aug 2020 16:21:39

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '28 Aug 2020 12:11'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '28 Aug 2020 14:41'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b32ec790-9b2d-433b-b3c6-1c19a757260a' User entered 'Yes (Y)'	System	28 Aug 2020 19:50:37
	System	28 Aug 2020 19:50:37

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b32ec790-9b2d-433b-b3c6-1c19a757260a' User entered '98.3'	System	28 Aug 2020 19:50:37
	System	28 Aug 2020 19:50:37

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b32ec790-9b2d-433b-b3c6-1c19a757260a' User entered 'No (N)'	System	28 Aug 2020 19:50:37
	System	28 Aug 2020 19:50:37

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b32ec790-9b2d-433b-b3c6-1c19a757260a' User entered '28 Aug 2020 15:50'	System	28 Aug 2020 19:50:37
	System	28 Aug 2020 19:50:37

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '28 Aug 2020 15:36'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 2'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:11', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1eb6e39b-0409-4d31-ba04-a1eb7c69337b' User entered 'Yes (Y)'	System	30 Aug 2020 01:06:28
	System	30 Aug 2020 01:06:28

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1eb6e39b-0409-4d31-ba04-a1eb7c69337b' User entered '97.9'	System	30 Aug 2020 01:06:28
	System	30 Aug 2020 01:06:28

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1eb6e39b-0409-4d31-ba04-a1eb7c69337b' User entered 'No (N)'	System	30 Aug 2020 01:06:28
	System	30 Aug 2020 01:06:28

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1eb6e39b-0409-4d31-ba04-a1eb7c69337b' User entered '29 Aug 2020 21:06'	System	30 Aug 2020 01:06:28
	System	30 Aug 2020 01:06:28

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 3'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0330b9d5-13a3-4d27-b191-af83261d123c' User entered 'Yes (Y)'	System	30 Aug 2020 17:46:29
	System	30 Aug 2020 17:46:29

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0330b9d5-13a3-4d27-b191-af83261d123c' User entered '98.5'	System	30 Aug 2020 17:46:29
	System	30 Aug 2020 17:46:29

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0330b9d5-13a3-4d27-b191-af83261d123c' User entered 'No (N)'	System	30 Aug 2020 17:46:29
	System	30 Aug 2020 17:46:29

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0330b9d5-13a3-4d27-b191-af83261d123c' User entered '30 Aug 2020 13:46'	System	30 Aug 2020 17:46:29
	System	30 Aug 2020 17:46:29

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 4'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '87692f5d-98ac-4ff3-816e-30499c6bf89d' User entered 'Yes (Y)'	System	31 Aug 2020 16:08:28
	System	31 Aug 2020 16:08:28

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '87692f5d-98ac-4ff3-816e-30499c6bf89d' User entered '97.6'	System	31 Aug 2020 16:08:28
	System	31 Aug 2020 16:08:28

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '87692f5d-98ac-4ff3-816e-30499c6bf89d'	System	31 Aug 2020 16:08:28
User entered 'No (N)'	System	31 Aug 2020 16:08:28

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '87692f5d-98ac-4ff3-816e-30499c6bf89d'	System	31 Aug 2020 16:08:28
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:08:28

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 5'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:01:57', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '17697e38-9c17-4ba2-96dd-bbfbe73955e0' User entered 'Yes (Y)'	System	01 Sep 2020 16:02:55
	System	01 Sep 2020 16:02:55

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:01', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '17697e38-9c17-4ba2-96dd-bbfbe73955e0' User entered '97.9'	System	01 Sep 2020 16:02:55
	System	01 Sep 2020 16:02:55

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '17697e38-9c17-4ba2-96dd-bbfbe73955e0' User entered 'No (N)'	System	01 Sep 2020 16:02:55
	System	01 Sep 2020 16:02:55

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:07', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '17697e38-9c17-4ba2-96dd-bbfbe73955e0' User entered '01 Sep 2020 12:02'	System	01 Sep 2020 16:02:55
	System	01 Sep 2020 16:02:55

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 6'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b91242db-3159-440d-9ee7-f57b7ff3366c' User entered 'Yes (Y)'	System	02 Sep 2020 16:04:01
	System	02 Sep 2020 16:04:01

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b91242db-3159-440d-9ee7-f57b7ff3366c' User entered '97.6'	System	02 Sep 2020 16:04:01
	System	02 Sep 2020 16:04:01

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b91242db-3159-440d-9ee7-f57b7ff3366c'	System	02 Sep 2020 16:04:01
User entered 'No (N)'	System	02 Sep 2020 16:04:01

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b91242db-3159-440d-9ee7-f57b7ff3366c' User entered '02 Sep 2020 12:03'	System	02 Sep 2020 16:04:01
	System	02 Sep 2020 16:04:01

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 7'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:05:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7c93739c-97ea-4acc-9a8b-3e6b024aa342' User entered 'Yes (Y)'	System	03 Sep 2020 16:07:30
	System	03 Sep 2020 16:07:30

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:05:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7c93739c-97ea-4acc-9a8b-3e6b024aa342' User entered '98.5'	System	03 Sep 2020 16:07:30
	System	03 Sep 2020 16:07:30

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:05:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7c93739c-97ea-4acc-9a8b-3e6b024aa342' User entered 'No (N)'	System	03 Sep 2020 16:07:30
	System	03 Sep 2020 16:07:30

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '7c93739c-97ea-4acc-9a8b-3e6b024aa342' User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:30
	System	03 Sep 2020 16:07:30

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424' User entered 'None (1)'	System	28 Aug 2020 16:22:45
	System	28 Aug 2020 16:22:45

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:21:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424' User entered 'No (N)'	System	28 Aug 2020 16:22:45
	System	28 Aug 2020 16:22:45

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424' User entered 'No (N)'	System	28 Aug 2020 16:22:45
	System	28 Aug 2020 16:22:45

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424' User entered 'None (1)'	System	28 Aug 2020 16:22:45
	System	28 Aug 2020 16:22:45

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c6954a-f987-4576-b24c-1608b2d37424' User entered '28 Aug 2020 12:22'	System	28 Aug 2020 16:22:45
	System	28 Aug 2020 16:22:45

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '28 Aug 2020 12:11'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '28 Aug 2020 14:41'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:50:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b' User entered 'None (1)'	System	28 Aug 2020 19:51:11
	System	28 Aug 2020 19:51:11

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:01', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b' User entered 'No (N)'	System	28 Aug 2020 19:51:11
	System	28 Aug 2020 19:51:11

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:03', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b' User entered 'No (N)'	System	28 Aug 2020 19:51:11
	System	28 Aug 2020 19:51:11

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:06', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b' User entered 'None (1)'	System	28 Aug 2020 19:51:11
	System	28 Aug 2020 19:51:11

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'cc7b5ea2-3d64-44b8-895e-81d6a4ee4c4b' User entered '28 Aug 2020 15:51'	System	28 Aug 2020 19:51:11
	System	28 Aug 2020 19:51:11

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '28 Aug 2020 15:36'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 2'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8'	System	30 Aug 2020 01:06:40
User entered 'None (1)'	System	30 Aug 2020 01:06:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8'	System	30 Aug 2020 01:06:40
User entered 'No (N)'	System	30 Aug 2020 01:06:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8' User entered 'No (N)'	System	30 Aug 2020 01:06:40
	System	30 Aug 2020 01:06:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8'	System	30 Aug 2020 01:06:40
User entered 'None (1)'	System	30 Aug 2020 01:06:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '514bc751-c657-4bf8-bffa-d450af41dda8'	System	30 Aug 2020 01:06:40
User entered '29 Aug 2020 21:06'	System	30 Aug 2020 01:06:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 3'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe'	System	30 Aug 2020 17:46:40
User entered 'None (1)'	System	30 Aug 2020 17:46:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe'	System	30 Aug 2020 17:46:40
User entered 'No (N)'	System	30 Aug 2020 17:46:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe' User entered 'No (N)'	System	30 Aug 2020 17:46:40
	System	30 Aug 2020 17:46:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe'	System	30 Aug 2020 17:46:40
User entered 'None (1)'	System	30 Aug 2020 17:46:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a758f844-858c-4735-b846-9b0f8e805cfe'	System	30 Aug 2020 17:46:40
User entered '30 Aug 2020 13:46'	System	30 Aug 2020 17:46:40

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 4'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c'	System	31 Aug 2020 16:08:48
User entered 'None (1)'	System	31 Aug 2020 16:08:48

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c' User entered 'No (N)'	System	31 Aug 2020 16:08:48
	System	31 Aug 2020 16:08:48

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c' User entered 'No (N)'	System	31 Aug 2020 16:08:48
	System	31 Aug 2020 16:08:48

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c' User entered 'None (1)'	System	31 Aug 2020 16:08:48
	System	31 Aug 2020 16:08:48

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0618fe36-e115-4504-9284-9b8d96ab486c' User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:08:48
	System	31 Aug 2020 16:08:48

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 5'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdfec612'	System	01 Sep 2020 16:03:08
User entered 'None (1)'	System	01 Sep 2020 16:03:08

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdfec612'	System	01 Sep 2020 16:03:08
User entered 'No (N)'	System	01 Sep 2020 16:03:08

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:15', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdfec612'	System	01 Sep 2020 16:03:08
User entered 'No (N)'	System	01 Sep 2020 16:03:08

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdfec612'	System	01 Sep 2020 16:03:08
User entered 'None (1)'	System	01 Sep 2020 16:03:08

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd8487881-2f8e-4ffb-a19d-90efdffec612'	System	01 Sep 2020 16:03:08
User entered '01 Sep 2020 12:02'	System	01 Sep 2020 16:03:08

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 6'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de' User entered 'None (1)'	System	02 Sep 2020 16:04:14
	System	02 Sep 2020 16:04:14

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de' User entered 'No (N)'	System	02 Sep 2020 16:04:14
	System	02 Sep 2020 16:04:14

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de' User entered 'No (N)'	System	02 Sep 2020 16:04:14
	System	02 Sep 2020 16:04:14

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de'	System	02 Sep 2020 16:04:14
User entered 'None (1)'	System	02 Sep 2020 16:04:14

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '47da36b6-fcea-4d58-8bfc-79e42e3cb5de' User entered '02 Sep 2020 12:03'	System	02 Sep 2020 16:04:14
	System	02 Sep 2020 16:04:14

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 7'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838'	System	03 Sep 2020 16:07:41
User entered 'None (1)'	System	03 Sep 2020 16:07:41

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:07', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838' User entered 'No (N)'	System	03 Sep 2020 16:07:41
	System	03 Sep 2020 16:07:41

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838' User entered 'No (N)'	System	03 Sep 2020 16:07:41
	System	03 Sep 2020 16:07:41

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:11', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838'	System	03 Sep 2020 16:07:41
User entered 'None (1)'	System	03 Sep 2020 16:07:41

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '805d6a37-e3b1-4fd2-acad-09573ca02838' User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:41
	System	03 Sep 2020 16:07:41

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b' User entered 'None (0)'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b' User entered 'None (0)'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b' User entered 'None (0)'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b' User entered 'None (0)'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:56', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b' User entered 'None (0)'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:22:58', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b' User entered 'None (0)'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:23:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b'	System	28 Aug 2020 16:23:08
User entered 'No (N)'	System	28 Aug 2020 16:23:08

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T12:23:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b8ffeb59-d91f-4a9d-8925-3e75447e5c7b' User entered '28 Aug 2020 12:23'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '28 Aug 2020 12:11'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '28 Aug 2020 14:41'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da' User entered 'None (0)'	System	28 Aug 2020 19:51:30
	System	28 Aug 2020 19:51:30

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da' User entered 'None (0)'	System	28 Aug 2020 19:51:30
	System	28 Aug 2020 19:51:30

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da' User entered 'None (0)'	System	28 Aug 2020 19:51:30
	System	28 Aug 2020 19:51:30

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da' User entered 'None (0)'	System	28 Aug 2020 19:51:30
	System	28 Aug 2020 19:51:30

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:21', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da' User entered 'None (0)'	System	28 Aug 2020 19:51:30
	System	28 Aug 2020 19:51:30

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da' User entered 'None (0)'	System	28 Aug 2020 19:51:30
	System	28 Aug 2020 19:51:30

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da'	System	28 Aug 2020 19:51:30
User entered 'No (N)'	System	28 Aug 2020 19:51:30

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-28T15:51:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ca854bfa-e86f-45d6-95c8-066e49b0a9da' User entered '28 Aug 2020 15:51'	System	28 Aug 2020 19:51:30
	System	28 Aug 2020 19:51:30

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '28 Aug 2020 15:36'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 2'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'None (0)'	System	30 Aug 2020 01:06:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'None (0)'	System	30 Aug 2020 01:06:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65' User entered 'None (0)'	System	30 Aug 2020 01:06:59
	System	30 Aug 2020 01:06:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65' User entered 'None (0)'	System	30 Aug 2020 01:06:59
	System	30 Aug 2020 01:06:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'None (0)'	System	30 Aug 2020 01:06:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65' User entered 'None (0)'	System	30 Aug 2020 01:06:59
	System	30 Aug 2020 01:06:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered 'No (N)'	System	30 Aug 2020 01:06:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-29T21:06:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed0b0203-00ea-4f44-8e19-2746f2f87a65'	System	30 Aug 2020 01:06:59
User entered '29 Aug 2020 21:06'	System	30 Aug 2020 01:06:59

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 3'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:42', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7' User entered 'None (0)'	System	30 Aug 2020 17:46:57
	System	30 Aug 2020 17:46:57

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7' User entered 'None (0)'	System	30 Aug 2020 17:46:57
	System	30 Aug 2020 17:46:57

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7' User entered 'None (0)'	System	30 Aug 2020 17:46:57
	System	30 Aug 2020 17:46:57

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:47', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7' User entered 'None (0)'	System	30 Aug 2020 17:46:57
	System	30 Aug 2020 17:46:57

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:49', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7' User entered 'None (0)'	System	30 Aug 2020 17:46:57
	System	30 Aug 2020 17:46:57

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7' User entered 'None (0)'	System	30 Aug 2020 17:46:57
	System	30 Aug 2020 17:46:57

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:53', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7'	System	30 Aug 2020 17:46:57
User entered 'No (N)'	System	30 Aug 2020 17:46:57

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-30T13:46:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a038e983-38ad-4db7-83f0-ed85cafca2b7' User entered '30 Aug 2020 13:46'	System	30 Aug 2020 17:46:57
	System	30 Aug 2020 17:46:57

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 4'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e' User entered 'None (0)'	System	31 Aug 2020 16:09:00
	System	31 Aug 2020 16:09:00

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e' User entered 'None (0)'	System	31 Aug 2020 16:09:00
	System	31 Aug 2020 16:09:00

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e' User entered 'None (0)'	System	31 Aug 2020 16:09:00
	System	31 Aug 2020 16:09:00

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e' User entered 'None (0)'	System	31 Aug 2020 16:09:00
	System	31 Aug 2020 16:09:00

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e' User entered 'None (0)'	System	31 Aug 2020 16:09:00
	System	31 Aug 2020 16:09:00

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e' User entered 'None (0)'	System	31 Aug 2020 16:09:00
	System	31 Aug 2020 16:09:00

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:55', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e' User entered 'No (N)'	System	31 Aug 2020 16:09:00
	System	31 Aug 2020 16:09:00

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-08-31T12:04:57', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '61505483-51fd-4f75-a043-9f8bb0605b7e' User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:09:00
	System	31 Aug 2020 16:09:00

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 5'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f' User entered 'None (0)'	System	01 Sep 2020 16:03:21
	System	01 Sep 2020 16:03:21

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f' User entered 'None (0)'	System	01 Sep 2020 16:03:21
	System	01 Sep 2020 16:03:21

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f' User entered 'None (0)'	System	01 Sep 2020 16:03:21
	System	01 Sep 2020 16:03:21

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f' User entered 'None (0)'	System	01 Sep 2020 16:03:21
	System	01 Sep 2020 16:03:21

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f' User entered 'None (0)'	System	01 Sep 2020 16:03:21
	System	01 Sep 2020 16:03:21

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f' User entered 'None (0)'	System	01 Sep 2020 16:03:21
	System	01 Sep 2020 16:03:21

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f' User entered 'No (N)'	System	01 Sep 2020 16:03:21
	System	01 Sep 2020 16:03:21

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-01T12:02:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a3e5aa52-802b-486d-968d-9348cef3330f' User entered '01 Sep 2020 12:02'	System	01 Sep 2020 16:03:21
	System	01 Sep 2020 16:03:21

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 6'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92' User entered 'None (0)'	System	02 Sep 2020 16:04:24
	System	02 Sep 2020 16:04:24

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered 'None (0)'	System	02 Sep 2020 16:04:24

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:43', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92' User entered 'None (0)'	System	02 Sep 2020 16:04:24
	System	02 Sep 2020 16:04:24

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92' User entered 'None (0)'	System	02 Sep 2020 16:04:24
	System	02 Sep 2020 16:04:24

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:46', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92' User entered 'None (0)'	System	02 Sep 2020 16:04:24
	System	02 Sep 2020 16:04:24

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:48', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92' User entered 'None (0)'	System	02 Sep 2020 16:04:24
	System	02 Sep 2020 16:04:24

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:50', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92'	System	02 Sep 2020 16:04:24
User entered 'No (N)'	System	02 Sep 2020 16:04:24

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-02T12:03:52', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '71f5cf57-b0f6-4c26-9db8-ad98abc33a92' User entered '02 Sep 2020 12:03'	System	02 Sep 2020 16:04:24
	System	02 Sep 2020 16:04:24

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	28 Aug 2020 16:20:07
User entered 'Day 7'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:18', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791' User entered 'None (0)'	System	03 Sep 2020 16:07:52
	System	03 Sep 2020 16:07:52

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791' User entered 'None (0)'	System	03 Sep 2020 16:07:52
	System	03 Sep 2020 16:07:52

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791' User entered 'None (0)'	System	03 Sep 2020 16:07:52
	System	03 Sep 2020 16:07:52

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:33', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791' User entered 'None (0)'	System	03 Sep 2020 16:07:52
	System	03 Sep 2020 16:07:52

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791' User entered 'None (0)'	System	03 Sep 2020 16:07:52
	System	03 Sep 2020 16:07:52

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:37', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791' User entered 'None (0)'	System	03 Sep 2020 16:07:52
	System	03 Sep 2020 16:07:52

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791'	System	03 Sep 2020 16:07:52
User entered 'No (N)'	System	03 Sep 2020 16:07:52

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-09-03T12:06:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b26a2e88-f235-4ca1-83cb-1ec231bdf791' User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:52
	System	03 Sep 2020 16:07:52

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:20:07

US3722066

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:20:07

US3722066

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	11 Sep 2020 18:59:51

US3722066

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '7 Sep 2020'	Kayla Peay (b) (4)	11 Sep 2020 18:59:51

US3722066

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	11 Sep 2020 18:59:51

US3722066

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered empty.	Kayla Peay (b) (4)	11 Sep 2020 18:59:51

US3722066

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	11 Sep 2020 18:59:54

US3722066

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'I'	System	11 Sep 2020 18:59:54

US3722066

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	11 Sep 2020 19:00:06

US3722066

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '11 Sep 2020'	Kayla Peay (b) (4)	11 Sep 2020 19:00:06

US3722066

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	11 Sep 2020 19:00:06

US3722066

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered empty.	Kayla Peay (b) (4)	11 Sep 2020 19:00:06

US3722066

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	11 Sep 2020 19:00:11

US3722066

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'I'	System	11 Sep 2020 19:00:11

US3722066

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	18 Sep 2020 17:35:13

US3722066

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered '18 Sep 2020'	Kayla Peay (b) (4)	18 Sep 2020 17:35:13

US3722066

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	18 Sep 2020 17:35:13

US3722066

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered empty.	Kayla Peay (b) (4)	18 Sep 2020 17:35:13

US3722066

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:02
User entered 'Yes (Y)'	Kayla Peay (b) (4)	18 Sep 2020 17:35:16

US3722066

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'I'	System	18 Sep 2020 17:35:16

US3722066

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	25 Sep 2020 14:48:02

US3722066

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '25 Sep 2020'	Kayla Peay (b) (4)	25 Sep 2020 14:48:02

US3722066

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Clinic (Clinic)'	Kayla Peay (b) (4)	25 Sep 2020 14:48:02

US3722066

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'VISIT3'	System	25 Sep 2020 14:48:02

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '25 Sep 2020'	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '09:01'	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered '25 Sep 2020 09:01'	System	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '98.4' F	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered empty.	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '69'	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'bpm'	System	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '16'	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'breaths/min'	System	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '143'	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'mmHg'	System	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '81'	Kayla Peay (b) (4)	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'mmHg'	System	25 Sep 2020 14:48:28

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51

US3722066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51

US3722066

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	25 Sep 2020 14:48:33

US3722066

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '25 Sep 2020'	Kayla Peay (b) (4)	25 Sep 2020 14:48:33

US3722066

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	25 Sep 2020 14:48:42

US3722066

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '25 Sep 2020'	Kayla Peay (b) (4)	25 Sep 2020 14:48:42

US3722066

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered '09:38'	Kayla Peay (b) (4)	25 Sep 2020 14:48:42

US3722066

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered '25 Sep 2020 09:38'	System	25 Sep 2020 14:48:42

US3722066

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:58:07
User entered 'Yes (Y)'	Kayla Peay (b) (4)	25 Sep 2020 14:48:45

US3722066

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'I'	System	25 Sep 2020 14:48:45

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 64'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-03T11:19:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0aaa5a2e-bd7e-4ac7-9a1f-d064597b5101' User entered 'No (N)'	System	03 Oct 2020 15:19:29
	System	03 Oct 2020 15:19:29

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-03T11:19:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0aaa5a2e-bd7e-4ac7-9a1f-d064597b5101' User entered 'No (N)'	System	03 Oct 2020 15:19:29
	System	03 Oct 2020 15:19:29

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-03T11:19:27', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '0aaa5a2e-bd7e-4ac7-9a1f-d064597b5101' User entered '03 Oct 2020 11:19:27'	System	03 Oct 2020 15:19:29
	System	03 Oct 2020 15:19:29

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 71'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-10T00:07:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a3ae19-2aef-4b96-ac3c-7cb5308197f8'	System	10 Oct 2020 04:07:41
User entered 'No (N)'	System	10 Oct 2020 04:07:41

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-10T00:07:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a3ae19-2aef-4b96-ac3c-7cb5308197f8'	System	10 Oct 2020 04:07:41
User entered 'No (N)'	System	10 Oct 2020 04:07:41

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-10T00:07:39', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f2a3ae19-2aef-4b96-ac3c-7cb5308197f8' User entered '10 Oct 2020 00:07:39'	System	10 Oct 2020 04:07:41
	System	10 Oct 2020 04:07:41

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 78'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-17T15:05:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'dac4aa5d-297c-486d-a6fa-777ea2255bb6'	System	17 Oct 2020 19:05:38
User entered 'No (N)'	System	17 Oct 2020 19:05:38

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-17T15:05:30', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'dac4aa5d-297c-486d-a6fa-777ea2255bb6'	System	17 Oct 2020 19:05:38
User entered 'No (N)'	System	17 Oct 2020 19:05:38

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-17T15:05:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'dac4aa5d-297c-486d-a6fa-777ea2255bb6' User entered '17 Oct 2020 15:05:32'	System	17 Oct 2020 19:05:38
	System	17 Oct 2020 19:05:38

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 92'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-31T02:13:14', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '524bfdaa-0ca4-449a-b61c-fa7bda85758b' User entered 'No (N)'	System	31 Oct 2020 07:13:37
	System	31 Oct 2020 07:13:37

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-31T02:13:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '524bfdaa-0ca4-449a-b61c-fa7bda85758b'	System	31 Oct 2020 07:13:37
User entered 'No (N)'	System	31 Oct 2020 07:13:37

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C8CF02BB-1DC9-4D81-B998-FDF78BCA07C3)', Time: '2020-10-31T02:13:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '524bfdaa-0ca4-449a-b61c-fa7bda85758b' User entered '31 Oct 2020 02:13:34'	System	31 Oct 2020 07:13:37
	System	31 Oct 2020 07:13:37

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 99'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:05:39
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered 'Day 106'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:25:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'Yes (Y)'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:25:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'No (N)'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:25:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'Yes (Y)'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '1'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered '1'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '1'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '1'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '0'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '1'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '1'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '1'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '1'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '0'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '0'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '0'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '0'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '0'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '0'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '0'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:05', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '0'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:26:59', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13'	System	14 Nov 2020 05:27:14
User entered 'No (N)'	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-14T00:27:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f234f512-7c7f-4200-90cb-ce743ced5f13' User entered '14 Nov 2020 00:27:04'	System	14 Nov 2020 05:27:14
	System	14 Nov 2020 05:27:14

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 21:49:25

US3722066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:59:29
Data entry locked.	System	03 Aug 2020 21:49:25
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 21:49:25

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T08:59:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered 'Yes (Y)'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T08:59:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered 'No (N)'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T08:59:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered 'Yes (Y)'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '1'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '1'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '1'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '1'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '0'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '1'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:17', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered 'Yes (Y)'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a'	System	21 Nov 2020 14:00:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-21T09:00:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '63ca6a6a-40d6-4892-92ae-0e65afe49e4a' User entered '21 Nov 2020 09:00:32'	System	21 Nov 2020 14:00:47
	System	21 Nov 2020 14:00:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-25T11:14:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1d4125f5-98ab-4b90-9a4c-8a053f86f05e' User entered 'No (N)'	System	25 Nov 2020 16:14:20
	System	25 Nov 2020 16:14:20

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-25T11:14:15', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1d4125f5-98ab-4b90-9a4c-8a053f86f05e' User entered 'No (N)'	System	25 Nov 2020 16:14:20

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-11-25T11:14:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '1d4125f5-98ab-4b90-9a4c-8a053f86f05e' User entered '25 Nov 2020 11:14:19'	System	25 Nov 2020 16:14:20
	System	25 Nov 2020 16:14:20

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-04T12:48:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c261514e-8a7b-4b0f-9951-bdea852593b1' User entered 'No (N)'	System	04 Dec 2020 17:48:37
	System	04 Dec 2020 17:48:37

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-04T12:48:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c261514e-8a7b-4b0f-9951-bdea852593b1' User entered 'No (N)'	System	04 Dec 2020 17:48:37
	System	04 Dec 2020 17:48:37

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-04T12:48:35', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c261514e-8a7b-4b0f-9951-bdea852593b1' User entered '04 Dec 2020 12:48:35'	System	04 Dec 2020 17:48:37

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-09T00:01:32', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b363e9d3-fd46-4c9b-a33a-3266cd55d32a' User entered 'No (N)'	System	09 Dec 2020 05:01:53
	System	09 Dec 2020 05:01:53

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-09T00:01:40', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b363e9d3-fd46-4c9b-a33a-3266cd55d32a' User entered 'No (N)'	System	09 Dec 2020 05:01:53
	System	09 Dec 2020 05:01:53

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-09T00:01:44', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b363e9d3-fd46-4c9b-a33a-3266cd55d32a' User entered '09 Dec 2020 00:01:44'	System	09 Dec 2020 05:01:53
	System	09 Dec 2020 05:01:53

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-16T00:29:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2d158654-1a3a-49bc-9809-eac662ce57c9' User entered 'No (N)'	System	16 Dec 2020 05:29:45
	System	16 Dec 2020 05:29:45

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-16T00:29:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2d158654-1a3a-49bc-9809-eac662ce57c9' User entered 'No (N)'	System	16 Dec 2020 05:29:45
	System	16 Dec 2020 05:29:45

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-16T00:29:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '2d158654-1a3a-49bc-9809-eac662ce57c9' User entered '16 Dec 2020 00:29:41'	System	16 Dec 2020 05:29:45
	System	16 Dec 2020 05:29:45

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:02', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff'	System	23 Dec 2020 22:14:10
User entered 'Yes (Y)'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:10', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff'	System	23 Dec 2020 22:14:10
User entered 'Yes (Y)'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:20', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff'	System	23 Dec 2020 22:14:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered 'Yes (Y)'	System	23 Dec 2020 22:14:10
	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10
	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '1'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '1'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '1'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '1'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10
	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10
	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10
	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10
	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '1'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10
	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '0'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:45', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff'	System	23 Dec 2020 22:14:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:51', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered 'Yes (Y)'	System	23 Dec 2020 22:14:10
	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:54', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff'	System	23 Dec 2020 22:14:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-23T17:13:57', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e10c360e-93dc-423e-b50b-c12d38c8faff' User entered '23 Dec 2020 17:13:57'	System	23 Dec 2020 22:14:10
	System	23 Dec 2020 22:14:10

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-30T01:38:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'dd6dd033-6f8d-41da-a97b-f8d7a83f7bda' User entered 'No (N)'	System	30 Dec 2020 06:38:43
	System	30 Dec 2020 06:38:43

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-30T01:38:38', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'dd6dd033-6f8d-41da-a97b-f8d7a83f7bda' User entered 'No (N)'	System	30 Dec 2020 06:38:43
	System	30 Dec 2020 06:38:43

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2020-12-30T01:38:41', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'dd6dd033-6f8d-41da-a97b-f8d7a83f7bda' User entered '30 Dec 2020 01:38:41'	System	30 Dec 2020 06:38:43
	System	30 Dec 2020 06:38:43

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-06T01:11:01', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '6c3a7258-90cc-4d4b-930d-d69a7c3fe398' User entered 'No (N)'	System	06 Jan 2021 06:11:11
	System	06 Jan 2021 06:11:11

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-06T01:11:04', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '6c3a7258-90cc-4d4b-930d-d69a7c3fe398'	System	06 Jan 2021 06:11:11
User entered 'No (N)'	System	06 Jan 2021 06:11:11

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-06T01:11:08', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '6c3a7258-90cc-4d4b-930d-d69a7c3fe398' User entered '06 Jan 2021 01:11:08'	System	06 Jan 2021 06:11:11
	System	06 Jan 2021 06:11:11

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-13T03:14:09', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a0172795-7190-4a14-a8c3-18a177eeb31a' User entered 'No (N)'	System	13 Jan 2021 08:14:19
	System	13 Jan 2021 08:14:19

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-13T03:14:12', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a0172795-7190-4a14-a8c3-18a177eeb31a' User entered 'No (N)'	System	13 Jan 2021 08:14:19

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-13T03:14:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'a0172795-7190-4a14-a8c3-18a177eeb31a' User entered '13 Jan 2021 03:14:16'	System	13 Jan 2021 08:14:19
	System	13 Jan 2021 08:14:19

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-20T00:02:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c91b1c33-4e63-4ea2-a7eb-e57ae806e7d2'	System	29 Jan 2021 20:03:40
User entered 'No (N)'	System	29 Jan 2021 20:03:40

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-20T00:02:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c91b1c33-4e63-4ea2-a7eb-e57ae806e7d2'	System	29 Jan 2021 20:03:40
User entered 'No (N)'	System	29 Jan 2021 20:03:40

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-20T00:02:29', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'c91b1c33-4e63-4ea2-a7eb-e57ae806e7d2'	System	29 Jan 2021 20:03:40
User entered '20 Jan 2021 00:02:29'	System	29 Jan 2021 20:03:40

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-29T15:03:19', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f23f7a3a-6082-43b5-9e03-27bffab05ee2' User entered 'No (N)'	System	29 Jan 2021 20:03:46
	System	29 Jan 2021 20:03:46

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-29T15:03:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f23f7a3a-6082-43b5-9e03-27bffab05ee2'	System	29 Jan 2021 20:03:46
User entered 'No (N)'	System	29 Jan 2021 20:03:46

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-01-29T15:03:26', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'f23f7a3a-6082-43b5-9e03-27bffab05ee2' User entered '29 Jan 2021 15:03:26'	System	29 Jan 2021 20:03:46
	System	29 Jan 2021 20:03:46

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-03T01:40:24', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '520ad121-f654-4d24-8a5a-d5e928878e92'	System	03 Feb 2021 06:40:42
User entered 'No (N)'	System	03 Feb 2021 06:40:42

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-03T01:40:31', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '520ad121-f654-4d24-8a5a-d5e928878e92'	System	03 Feb 2021 06:40:42
User entered 'No (N)'	System	03 Feb 2021 06:40:42

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-03T01:40:34', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '520ad121-f654-4d24-8a5a-d5e928878e92'	System	03 Feb 2021 06:40:42
User entered '03 Feb 2021 01:40:34'	System	03 Feb 2021 06:40:42

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-10T00:32:23', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed8223a2-f3df-4c45-a2f2-6493e6b20515'	System	10 Feb 2021 05:32:39
User entered 'No (N)'	System	10 Feb 2021 05:32:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-10T00:32:28', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed8223a2-f3df-4c45-a2f2-6493e6b20515'	System	10 Feb 2021 05:32:39
User entered 'No (N)'	System	10 Feb 2021 05:32:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-10T00:32:36', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ed8223a2-f3df-4c45-a2f2-6493e6b20515' User entered '10 Feb 2021 00:32:36'	System	10 Feb 2021 05:32:39
	System	10 Feb 2021 05:32:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-17T00:01:16', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c85e36-24a7-4ebc-a9ab-b6b51f55c057'	System	17 Feb 2021 05:03:01
User entered 'No (N)'	System	17 Feb 2021 05:03:01

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-17T00:01:22', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c85e36-24a7-4ebc-a9ab-b6b51f55c057'	System	17 Feb 2021 05:03:01
User entered 'No (N)'	System	17 Feb 2021 05:03:01

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-17T00:01:25', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '54c85e36-24a7-4ebc-a9ab-b6b51f55c057'	System	17 Feb 2021 05:03:01
User entered '17 Feb 2021 00:01:25'	System	17 Feb 2021 05:03:01

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-24T00:01:24-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'df544fa7-4e86-4650-a794-dcf5294ff87d' User entered 'No (N)'	System	24 Feb 2021 05:02:53
	System	24 Feb 2021 05:02:53

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-24T00:01:27-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'df544fa7-4e86-4650-a794-dcf5294ff87d' User entered 'No (N)'	System	24 Feb 2021 05:02:53
	System	24 Feb 2021 05:02:53

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-02-24T00:01:32-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'df544fa7-4e86-4650-a794-dcf5294ff87d' User entered '24 Feb 2021 05:01:32'	System	24 Feb 2021 05:02:53
	System	24 Feb 2021 05:02:53

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-05T12:10:14-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '6ee57b64-007e-4375-b3ea-da44f82fda74'	System	05 Mar 2021 17:19:48
User entered 'No (N)'	System	05 Mar 2021 17:19:48

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-05T12:10:18-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '6ee57b64-007e-4375-b3ea-da44f82fda74'	System	05 Mar 2021 17:19:48
User entered 'No (N)'	System	05 Mar 2021 17:19:48

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-05T12:10:22-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '6ee57b64-007e-4375-b3ea-da44f82fda74' User entered '05 Mar 2021 12:10:22'	System	05 Mar 2021 17:19:48
	System	05 Mar 2021 17:19:48

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-10T00:20:40-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9ada5890-f2f2-4a81-bd53-88a268fc2f13'	System	10 Mar 2021 05:20:55
User entered 'No (N)'	System	10 Mar 2021 05:20:55

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-10T00:20:44-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9ada5890-f2f2-4a81-bd53-88a268fc2f13'	System	10 Mar 2021 05:20:55
User entered 'No (N)'	System	10 Mar 2021 05:20:55

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-10T00:20:51-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '9ada5890-f2f2-4a81-bd53-88a268fc2f13' User entered '10 Mar 2021 00:20:51'	System	10 Mar 2021 05:20:55
	System	10 Mar 2021 05:20:55

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-17T01:14:02-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b237ad89-131d-4120-b66f-bca44852ee41'	System	17 Mar 2021 05:14:14
User entered 'No (N)'	System	17 Mar 2021 05:14:14

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-17T01:14:08-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b237ad89-131d-4120-b66f-bca44852ee41'	System	17 Mar 2021 05:14:14
User entered 'No (N)'	System	17 Mar 2021 05:14:14

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-17T01:14:12-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'b237ad89-131d-4120-b66f-bca44852ee41'	System	17 Mar 2021 05:14:14
User entered '17 Mar 2021 01:14:12'	System	17 Mar 2021 05:14:14

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-24T00:02:21-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '96e63ac6-cd14-4e36-9eb9-f8e69c84423c' User entered 'No (N)'	System	24 Mar 2021 04:03:23
	System	24 Mar 2021 04:03:23

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-24T00:02:25-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '96e63ac6-cd14-4e36-9eb9-f8e69c84423c' User entered 'No (N)'	System	24 Mar 2021 04:03:23
	System	24 Mar 2021 04:03:23

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-24T00:02:28-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '96e63ac6-cd14-4e36-9eb9-f8e69c84423c' User entered '24 Mar 2021 00:02:28'	System	24 Mar 2021 04:03:23
	System	24 Mar 2021 04:03:23

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-31T00:30:37-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e9ade92a-ec42-4be0-be3e-f1d438ca8eab'	System	31 Mar 2021 04:30:56
User entered 'No (N)'	System	31 Mar 2021 04:30:56

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-31T00:30:47-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e9ade92a-ec42-4be0-be3e-f1d438ca8eab'	System	31 Mar 2021 04:30:56
User entered 'No (N)'	System	31 Mar 2021 04:30:56

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-31T00:30:52-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'e9ade92a-ec42-4be0-be3e-f1d438ca8eab' User entered '31 Mar 2021 00:30:52'	System	31 Mar 2021 04:30:56
	System	31 Mar 2021 04:30:56

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-07T00:56:43-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5089a9b1-2909-4def-9c87-09a497eeee1f' User entered 'Yes (Y)'	System	07 Apr 2021 04:57:22

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-07T00:56:51-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5089a9b1-2909-4def-9c87-09a497eeee1f' User entered 'No (N)'	System	07 Apr 2021 04:57:22

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-07T00:57:00-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5089a9b1-2909-4def-9c87-09a497eeee1f' User entered 'No (N)'	System	07 Apr 2021 04:57:22

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-07T00:57:16-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5089a9b1-2909-4def-9c87-09a497eeee1f' User entered 'No (N)'	System	07 Apr 2021 04:57:22

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-07T00:57:20-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '5089a9b1-2909-4def-9c87-09a497eeee1f' User entered '07 Apr 2021 00:57:20'	System	07 Apr 2021 04:57:22
	System	07 Apr 2021 04:57:22

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-14T00:53:11-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd5075314-d455-4b0b-a2cb-b558b41be6d0'	System	14 Apr 2021 04:53:30
User entered 'No (N)'	System	14 Apr 2021 04:53:30

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-14T00:53:19-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd5075314-d455-4b0b-a2cb-b558b41be6d0'	System	14 Apr 2021 04:53:30
User entered 'No (N)'	System	14 Apr 2021 04:53:30

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-14T00:53:26-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'd5075314-d455-4b0b-a2cb-b558b41be6d0'	System	14 Apr 2021 04:53:30
User entered '14 Apr 2021 00:53:26'	System	14 Apr 2021 04:53:30

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-21T01:13:33-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ad37beae-3e99-42c7-bcb9-55ea6514627a' User entered 'No (N)'	System	21 Apr 2021 05:13:49
	System	21 Apr 2021 05:13:49

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-21T01:13:40-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ad37beae-3e99-42c7-bcb9-55ea6514627a' User entered 'No (N)'	System	21 Apr 2021 05:13:49
	System	21 Apr 2021 05:13:49

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-21T01:13:47-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'ad37beae-3e99-42c7-bcb9-55ea6514627a' User entered '21 Apr 2021 01:13:47'	System	21 Apr 2021 05:13:49
	System	21 Apr 2021 05:13:49

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-28T00:10:25-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '31549c53-d0e2-4e96-9f65-869336c1ebb5' User entered 'No (N)'	System	28 Apr 2021 04:44:47
	System	28 Apr 2021 04:44:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

Have you been exposed to someone with 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 (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-28T00:44:36-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '31549c53-d0e2-4e96-9f65-869336c1ebb5' User entered 'No (N)'	System	28 Apr 2021 04:44:47
	System	28 Apr 2021 04:44:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-04-28T00:44:43-04:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: '31549c53-d0e2-4e96-9f65-869336c1ebb5' User entered '28 Apr 2021 00:44:43'	System	28 Apr 2021 04:44:47
	System	28 Apr 2021 04:44:47

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:05:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:05:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:05:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:05:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:05:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:05:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:05:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 12:05:39

US3722066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:05:39
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 12:05:39

US3722066

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:32:46

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 03:24:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-05T12:10:28-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'eed0b827-386b-4911-9252-91821213d0a4'	System	05 Mar 2021 17:19:52
User entered 'No (N)'	System	05 Mar 2021 17:19:52

US3722066

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:32:46

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:24:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98A4DA25-CC70-43CC-9287-BBC1ADE06C7A)', Time: '2021-03-05T12:10:31-05:00', User OID: 'PatientReportedOutcome (US3722066)', ODM File OID: 'eed0b827-386b-4911-9252-91821213d0a4'	System	05 Mar 2021 17:19:52
User entered '05 Mar 2021 12:10:31'	System	05 Mar 2021 17:19:52

US3722066

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:15:25
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Nov 2020 18:32:15

US3722066

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:15:25
User entered '22 Oct 2020'	Marlee Smith (b) (4)	05 Nov 2020 18:32:15

US3722066

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:15:25
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	05 Nov 2020 18:32:15

US3722066

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:15:25
User entered empty.	Marlee Smith (b) (4)	05 Nov 2020 18:32:15

US3722066

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:15:25
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Nov 2020 18:32:17

US3722066

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:48:51
User entered 'I'	System	05 Nov 2020 18:32:17

US3722066

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:45
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Sara Poff (b) (4)	16 Nov 2020 14:17:44

US3722066

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:45
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '16 Nov 2020'	Sara Poff (b) (4)	16 Nov 2020 14:17:44

US3722066

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:45
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Contact Made (CONTACT MADE)'	Sara Poff (b) (4)	16 Nov 2020 14:17:44

US3722066

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:45
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per DM CLR: Review specified comment, REPORTED SOB, FEVER OF 102.6 AND MUSCLE ACHES. Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:21:32
Query 'Per DM CLR: Review specified comment, REPORTED SOB, FEVER OF 102.6 AND MUSCLE ACHES. Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate. ' answered with 'AE was made' (Site from DM).	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:29:14
User opened query 'Per DM CLR: Review specified comment, REPORTED SOB, FEVER OF 102.6 AND MUSCLE ACHES. Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 03:27:25
User entered 'Subject reported SOB, fever of 102.6 and muscle aches. Subject has been scheduled for a sick visit.'	Sara Poff (b) (4) (b) (4)	16 Nov 2020 14:17:44

US3722066

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:45
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Sara Poff (b) (4)	16 Nov 2020 14:17:54

US3722066

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:45
User entered 'I'	System	16 Nov 2020 14:17:54

US3722066

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	20 Jan 2021 13:53:01

US3722066

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '23 Dec 2020'	Marlee Smith (b) (4)	20 Jan 2021 13:53:01

US3722066

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	20 Jan 2021 13:53:01

US3722066

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Marlee Smith (b) (4)	20 Jan 2021 13:53:01

US3722066

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	20 Jan 2021 13:53:04

US3722066

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:18
User entered 'I'	System	20 Jan 2021 13:53:04

US3722066

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	25 Jan 2021 20:07:45

US3722066

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '25 Jan 2021'	Taylor Wilson (b) (4)	25 Jan 2021 20:07:45

US3722066

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	25 Jan 2021 20:07:45

US3722066

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Taylor Wilson (b) (4)	25 Jan 2021 20:07:45

US3722066

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	25 Jan 2021 20:07:51

US3722066

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:59
User entered 'I'	System	25 Jan 2021 20:07:51

US3722066

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Marlee Smith (b) (4)	03 Mar 2021 14:51:04

US3722066

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '3 Mar 2021'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:51:04
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	03 Mar 2021 14:51:04

US3722066

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'VISIT4'	System	03 Mar 2021 14:51:04

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Yes (Y)'	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '3 Mar 2021'	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '09:01'	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '3 Mar 2021 09:01'	System	29 Mar 2021 17:26:21

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '98.2' F	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered empty.	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '83'	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'bpm'	System	29 Mar 2021 17:26:21

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '16'	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'breaths/min'	System	29 Mar 2021 17:26:21

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '130'	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'mmHg'	System	29 Mar 2021 17:26:21

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '81'	Marlee Smith (b) (4)	29 Mar 2021 17:26:21
	(b) (4)	

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'mmHg'	System	29 Mar 2021 17:26:21

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17

US3722066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:06:37
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17

US3722066

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'No (N)'	Marlee Smith (b) (4)	03 Mar 2021 14:51:08

US3722066

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered empty.	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:51:08

US3722066

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	Marlee Smith (b) (4)	03 Mar 2021 14:51:17

US3722066

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '3 Mar 2021'	Marlee Smith (b) (4)	03 Mar 2021 14:51:17

US3722066

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered '09:09'	Marlee Smith (b) (4)	03 Mar 2021 14:51:17

US3722066

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered '3 Mar 2021 09:09'	System	03 Mar 2021 14:51:17

US3722066

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:16:09
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:51:21

US3722066

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:43:17
User entered 'I'	System	03 Mar 2021 14:51:21

US3722066

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	25 Mar 2021 14:41:24

US3722066

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '25 Mar 2021'	Taylor Wilson (b) (4)	25 Mar 2021 14:41:24

US3722066

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	25 Mar 2021 14:41:24

US3722066

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Taylor Wilson (b) (4)	25 Mar 2021 14:41:24

US3722066

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	25 Mar 2021 14:41:29

US3722066

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:12
User entered 'I'	System	25 Mar 2021 14:41:29

US3722066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	01 Apr 2021 18:20:52
	(b) (4)	

US3722066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 04:25:14
Query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Subject was contacted with in window of visit' (Site from System).	Taylor Wilson (b) (4) (b) (4)	01 Apr 2021 18:23:45
User opened query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Apr 2021 18:20:52
User entered '01 Apr 2021'	Taylor Wilson (b) (4) (b) (4)	01 Apr 2021 18:20:52

US3722066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	01 Apr 2021 18:20:52
	(b) (4)	

US3722066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
User entered empty.	Taylor Wilson (b) (4)	01 Apr 2021 18:20:52
	(b) (4)	

US3722066

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	01 Apr 2021 18:23:52
	(b) (4)	

US3722066

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 18:23:52

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:46

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:52:11
User closed query 'Please reconcile and enter missing severity page' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:35:12
Query 'Please reconcile and enter missing severity page' answered with 'Completed ' (Site from CRA).	Sara Poff (b) (4)	23 Nov 2020 18:52:53
User opened query 'Please reconcile and enter missing severity page' (Site from CRA).	(b) (4)	23 Nov 2020 15:54:59
User entered '16 Nov 2020'	(b) (4), (b) (6)	
	Sara Poff (b) (4)	18 Nov 2020 19:45:14
	(b) (4)	

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:46

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:33:15
User closed query 'Please verify time of contact, as first time entry in source appears to be 15:16.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:33:13
Query 'Please verify time of contact, as first time entry in source appears to be 15:16.' answered with 'Updated ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:32:52
User entered '15:16' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:32:45
User opened query 'Please verify time of contact, as first time entry in source appears to be 15:16.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:54:29
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:11
User entered '15:20'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:45:14

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:46

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:08
User entered '16 Nov 2020 15:16'	System	24 Nov 2020 00:32:45
User entered '16 Nov 2020 15:20'	System	18 Nov 2020 19:45:14

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:46

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:32:57
User closed query 'Per ETRTR: Please consider updating data point to "Clinic Visit - Unscheduled" because this was not a Protocol Scheduled visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 19:32:56
Query 'Per ETRTR: Please consider updating data point to "Clinic Visit - Unscheduled" because this was not a Protocol Scheduled visit, thanks.' answered with 'Updated ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	10 Dec 2020 20:46:40
DataPoint Un-verified.	Sara Poff (b) (4) (b) (4)	10 Dec 2020 20:46:31
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	10 Dec 2020 20:46:31
User opened query 'Per ETRTR: Please consider updating data point to "Clinic Visit - Unscheduled" because this was not a Protocol Scheduled visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 21:03:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:11
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:45:14

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:46

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:52:11
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:45:14

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Sara Poff (b) (4)	24 Nov 2020 00:41:25
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Sara Poff (b) (4)	24 Nov 2020 00:35:31
User entered 'Day 1 (Day 1)'	Sara Poff (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Please comment and clarify on the lack of diary entries from 17 Nov 2020 and forward. If the lack of completion is related to the subject's hospitalization, please confirm in query response if contacts with the site have occurred and their context.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:26
User closed query 'Thank you for your previous response. Please note that symptoms should be captured starting 11 NOV 2020 based on the start date of the initial AE. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 03:59:19
Query 'Thank you for your previous response. Please note that symptoms should be captured starting 11 NOV 2020 based on the start date of the initial AE. ' answered with 'updated ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:34:18
Query 'Please comment and clarify on the lack of diary entries from 17 Nov 2020 and forward. If the lack of completion is related to the subject's hospitalization, please confirm in query response if contacts with the site have occurred and their context.' answered with 'The reason for the lack of diary entries is due to the hospitalization ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:34:01
User opened query 'Please comment and clarify on the lack of diary entries from 17 Nov 2020 and forward. If the lack of completion is related to the subject's hospitalization, please confirm in query response if contacts with the site have occurred and their context.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:18:11
User opened query 'Thank you for your previous response. Please note that symptoms should be captured starting 11 NOV 2020 based on the start date of the initial AE. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:37
User closed query 'Please reconcile and enter all missing dates since 16Nov2020. As a reminder symptom log is to be updated within 24 hrs of daily illness call.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:37
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:10

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Date](#)

Audit	User	Time (GMT)
Query 'Please reconcile and enter all missing dates since 16Nov2020. As a reminder symptom log is to be updated within 24 hrs of daily illness call.' answered with 'Subject is in the hospital and we are unable to complete the symptom log at this time ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:56:32
User opened query 'Please reconcile and enter all missing dates since 16Nov2020. As a reminder symptom log is to be updated within 24 hrs of daily illness call.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:54:27
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered '0'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered '86'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User entered '%'	System	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered '98.7' F	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:14
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:02

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per sponsor review: According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis. Symptom log less than 14 days, please review and if applicable, add additional lines to record symptoms or marked assessment not done, or otherwise clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 06:02:20
Query 'Per sponsor review: According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis. Symptom log less than 14 days, please review and if applicable, add additional lines to record symptoms or marked assessment not done, or otherwise clarify' answered with 'Subject was admitted into the hospital. Staff could not get in contact with subject everyday and medical records don't record symptoms or how long they lasted. ' (Site from DM).	Marlee Smith (b) (4) (b) (4)	09 Apr 2021 12:30:03
User opened query 'Per sponsor review: According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis. Symptom log less than 14 days, please review and if applicable, add additional lines to record symptoms or marked assessment not done, or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:37:27
Query 'Per sponsor review: According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis. Symptom log less than 14 days, please review and reconcile or otherwise clarify' canceled (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:36:58
User opened query 'Per sponsor review: According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis. Symptom log less than 14 days, please review and reconcile or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:36:44
User entered 'Day 1 (Day 1)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '11 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User entered '%'	System	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:35:31

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Day 2 (Day 2)'	(b) (4) Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '12 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User entered '%'	System	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:36:34

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Day 3 (Day 3)'	Sara Poff (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '13 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User entered '%'	System	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:37:42

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Day 4 (Day 4)'	Sara Poff (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '14 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User entered '%'	System	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:38:48

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Day 5 (Day 5)'	Sara Poff (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '15 Nov 2020'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered '0'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User entered '%'	System	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered missing code ND - Not Done.	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Severe (Severe)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'Moderate (Moderate)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:59:34
User entered 'None (None)'	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:39:46

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered '16 Nov 2020'	Sara Poff (b) (4)	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:33:44
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:56:45
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Updated' (Site from System).	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:44
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	18 Nov 2020 19:48:26
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered empty.	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered empty.	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:33:44
User entered empty.	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:46

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:22
User entered 'I'	System	18 Nov 2020 19:48:26

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:32:46

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:32:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:32:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

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[Start Date](#)

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[End Date](#)

Audit	User	Time (GMT)
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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

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[Oxygen Saturation](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered '86'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

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[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
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[PaO2](#)

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[Did the subject have Respiratory failure?](#)

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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[High-Flow Oxygen?](#)

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[Non-Invasive Ventilation?](#)

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[Mechanical Ventilation?](#)

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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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[Evidence of Shock Requires
Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:32:46

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:32:46

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:32:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

US3722066

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:32:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:02:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:51
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:54:45

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:32:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User accepted default value 'Day 3 (Day 3)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:32:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:20
User entered 'No (N)'	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:32:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:20
User entered empty.	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:32:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User accepted default value 'Day 5 (Day 5)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:32:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:16
User entered 'No (N)'	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:32:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:16
User entered empty.	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:32:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User accepted default value 'Day 7 (Day 7)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:32:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:16
User entered 'No (N)'	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:32:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:16
User entered empty.	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:32:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User accepted default value 'Day 9 (Day 9)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:32:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:09
User entered 'No (N)'	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:32:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:09
User entered empty.	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:32:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User accepted default value 'Day 14 (Day 14)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:32:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:08
User entered 'No (N)'	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:32:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:08
User entered empty.	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:32:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User accepted default value 'Day 21 (Day 21)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:32:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:02
User entered 'No (N)'	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:32:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:02
User entered empty.	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:32:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User accepted default value 'Day 28 (Day 28)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:32:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:07:54
User entered 'Yes (Y)'	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:32:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:07:54
User entered '14 Dec 2020'	Sara Poff (b) (4)	14 Dec 2020 16:31:40

US3722066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:16
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:11
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:49:47

US3722066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:16
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per ETRTR: Please complete data entry within Saliva Collection page. If Collection was not done, state so within Saliva Collection Form, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:37:10
Query 'Per ETRTR: Please complete data entry within Saliva Collection page. If Collection was not done, state so within Saliva Collection Form, thanks.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 16:21:24
User opened query 'Per ETRTR: Please complete data entry within Saliva Collection page. If Collection was not done, state so within Saliva Collection Form, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 21:02:30
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:11
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 19:49:47

US3722066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:16
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:11
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	18 Nov 2020 19:49:47

US3722066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:16
User entered 'SICKD1'	System	18 Nov 2020 19:49:47

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '16 Nov 2020'	Sara Poff (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:08:26
User closed query 'Please verify time of assessment, as source indicates 15:20.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:08:24
Query 'Please verify time of assessment, as source indicates 15:20.' answered with 'Updated' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:40:50
User entered '15:20' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Nov 2020 00:40:42
User opened query 'Please verify time of assessment, as source indicates 15:20.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:41:25
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:40:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '15:26'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User entered '16 Nov 2020 15:20'	System	24 Nov 2020 00:40:42
User entered '16 Nov 2020 15:26'	System	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '167' cm	Sara Poff (b) (4)	18 Nov 2020 20:01:15
DataPoint set to visible.	(b) (4) System	18 Nov 2020 19:49:47

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '196' lb	Sara Poff (b) (4)	18 Nov 2020 20:01:15
DataPoint set to visible.	(b) (4) System	18 Nov 2020 19:49:47

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '98.7' F	Sara Poff (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered 'Oral (Oral)'	Sara Poff (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered empty.	Sara Poff (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '81'	Sara Poff (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User entered 'bpm'	System	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '24'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User entered 'breaths/min'	System	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '155'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User entered 'mmHg'	System	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:25
User entered '83'	Sara Poff (b) (4)	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31
User entered 'mmHg'	System	18 Nov 2020 20:01:15

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31

US3722066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:31

US3722066

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:41:58
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:40

US3722066

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:41:58
User entered '16 Nov 2020'	Sara Poff (b) (4)	18 Nov 2020 20:01:40

US3722066

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:32:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:42:05
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:49

US3722066

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:32:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:59:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:42:05
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	18 Nov 2020 20:01:49

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:39:23
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:32:21

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:39:23
User entered '14 Dec 2020'	Sara Poff (b) (4)	14 Dec 2020 16:32:21

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:39:23
User entered 'Clinic (Clinic)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:32:21

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:04
User entered 'SICKD28'	System	14 Dec 2020 16:32:21

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:09
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:40:06
User entered '14 Dec 2020'	Sara Poff (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 09:22:27
User closed query 'Per source, VS collection time was 10:02. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 09:22:23
Query 'Per source, VS collection time was 10:02. Please reconcile.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4)	21 Jan 2021 14:20:26
User entered '10:02' reason for change: Data Entry Error	(b) (4)	21 Jan 2021 14:20:14
User opened query 'Per source, VS collection time was 10:02. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 19:42:05
User entered '10:00'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User entered '14 Dec 2020 10:02'	System	21 Jan 2021 14:20:14
User entered '14 Dec 2020 10:00'	System	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:40:08
User entered '167' cm	Sara Poff (b) (4)	14 Dec 2020 16:34:07
DataPoint set to visible.	(b) (4) System	14 Dec 2020 16:32:21

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:40:03
User entered '196' lb	Sara Poff (b) (4)	14 Dec 2020 16:34:07
DataPoint set to visible.	(b) (4) System	14 Dec 2020 16:32:21

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:41:00
User entered '97.8' F	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:40:54
User entered 'Oral (Oral)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:40:59
User entered empty.	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:41:02
User entered '75'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User entered 'bpm'	System	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:41:04
User entered '20'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User entered 'breaths/min'	System	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:40:52
User entered '144'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User entered 'mmHg'	System	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:41:06
User entered '82'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13
User entered 'mmHg'	System	14 Dec 2020 16:34:07

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:13

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:26
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:32:10

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:26
User entered '14 Dec 2020'	Sara Poff (b) (4)	14 Dec 2020 16:32:10

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:32:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:35
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:32:01

US3722066

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:32:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:00:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:35
User entered '14 Dec 2020'	Sara Poff (b) (4)	14 Dec 2020 16:32:01

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	09 Jan 2021 18:52:00

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '9 Jan 2021'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:52:00

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	09 Jan 2021 18:52:00

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered 'UNBLND_DECIDE'	System	09 Jan 2021 18:52:00

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '9 Jan 2021'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '0'	(b) (4) Marlee Smith (b) (4)	22 Apr 2021 12:29:29
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:17:34

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 20:06:07
Query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 12:29:33
User entered 'Amendment 6 or later (Amendment 6 or later)'	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 12:29:29
User opened query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 05:18:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:17:34

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '9 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Placebo (Placebo)'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:06:22
User entered 'Placebo (Placebo)'	Marlee Smith (b) (4)	09 Jan 2021 18:52:10
	(b) (4)	

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:06:22
User entered 'Placebo (Placebo)'	Marlee Smith (b) (4)	09 Jan 2021 18:52:10
	(b) (4)	

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User entered '1'	System	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:32:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User entered 'I'	System	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered empty.	System	09 Jan 2021 18:53:45
DataPoint set to visible.	System	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:53:45
	(b) (4)	

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered empty.	System	09 Jan 2021 18:53:45
DataPoint set to visible.	System	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User accepted default value 'Pre-Dose (PREDOSE)'	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '9 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '13:08'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered '9 Jan 2021 13:08'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '98.1' F	Marlee Smith (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Oral (Oral)'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '75'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered 'bpm'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '15'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered 'breaths/min'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '139'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered 'mmHg'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '83'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered 'mmHg'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered empty.	System	09 Jan 2021 18:53:45
DataPoint set to visible.	System	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User accepted default value 'Post-Dose (POSTDOSE)'	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '9 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '13:44'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered '9 Jan 2021 13:44'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '98' F	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Oral (Oral)'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '75'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered 'bpm'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '16'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered 'breaths/min'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '140'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered 'mmHg'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '83'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:14
User entered 'mmHg'	System	09 Jan 2021 18:53:45

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:53:55

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '9 Jan 2021'	Marlee Smith (b) (4)	09 Jan 2021 18:53:55

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:54:04

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:54:04

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Marlee Smith (b) (4)	09 Jan 2021 18:54:04

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User entered 'mRNA-1273'	System	09 Jan 2021 18:54:04
DataPoint set to visible.	System	09 Jan 2021 18:52:10

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '9 Jan 2021'	Marlee Smith (b) (4)	09 Jan 2021 18:54:04

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '13:14'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:54:04

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User entered '9 Jan 2021 13:14'	System	09 Jan 2021 18:54:04

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Left Arm (LEFT ARM)'	Marlee Smith (b) (4)	09 Jan 2021 18:54:04

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User entered 'ONCE'	System	09 Jan 2021 18:54:04

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User entered 'INTRAMUSCULAR'	System	09 Jan 2021 18:54:04

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	09 Jan 2021 18:52:17

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '9 Jan 2021'	Marlee Smith (b) (4)	09 Jan 2021 18:52:17

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '12:10'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:52:17

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User entered '9 Jan 2021 12:10'	System	09 Jan 2021 18:52:17

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:52:27

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '9 Jan 2021'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:52:27

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '12:07'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Jan 2021 18:52:27

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:32:46

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User entered '9 Jan 2021 12:07'	System	09 Jan 2021 18:52:27

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	09 Jan 2021 18:52:30

US3722066

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:12
User entered 'I'	System	09 Jan 2021 18:52:30

US3722066

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:05:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	18 Jan 2021 18:42:04

US3722066

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:05:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '18 Jan 2021'	Taylor Wilson (b) (4)	18 Jan 2021 18:42:04

US3722066

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:05:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	18 Jan 2021 18:42:04

US3722066

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:05:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Taylor Wilson (b) (4)	18 Jan 2021 18:42:04

US3722066

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:05:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	18 Jan 2021 18:42:09

US3722066

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:05:06
User entered 'I'	System	18 Jan 2021 18:42:09

US3722066

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:05:06
User entered '1'	System	18 Jan 2021 18:42:09
DataPoint set to visible.	System	18 Jan 2021 18:42:09

US3722066

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	08 Feb 2021 13:22:35

US3722066

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '6 Feb 2021'	Marlee Smith (b) (4)	08 Feb 2021 13:22:35

US3722066

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	08 Feb 2021 13:22:35

US3722066

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'OLD29'	System	08 Feb 2021 13:22:35

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User accepted default value 'Pre-Dose (PREDOSE)'	Marlee Smith (b) (4) (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '6 Feb 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '08:46'	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered '6 Feb 2021 08:46'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '99.3' F	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '84'	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'bpm'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '18'	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'breaths/min'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '130'	(b) (4) Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'mmHg'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '76'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'mmHg'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User accepted default value 'Post-Dose (POSTDOSE)'	Marlee Smith (b) (4) (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '6 Feb 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '09:26'	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered '6 Feb 2021 09:26'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '98.7' F	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '79'	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'bpm'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '18'	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'breaths/min'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '123'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'mmHg'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '73'	Marlee Smith (b) (4)	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'mmHg'	System	08 Feb 2021 13:23:32

US3722066

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'No (N)'	Marlee Smith (b) (4)	08 Feb 2021 13:23:35

US3722066

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Marlee Smith (b) (4)	08 Feb 2021 13:23:35

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	08 Feb 2021 13:23:46

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4)	08 Feb 2021 13:23:46

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Marlee Smith (b) (4)	08 Feb 2021 13:23:46

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'mRNA-1273'	System	08 Feb 2021 13:23:46
DataPoint set to visible.	System	18 Jan 2021 18:42:09

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '6 Feb 2021'	Marlee Smith (b) (4)	08 Feb 2021 13:23:46

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '08:55'	Marlee Smith (b) (4)	08 Feb 2021 13:23:46

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered '6 Feb 2021 08:55'	System	08 Feb 2021 13:23:46

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Left Arm (LEFT ARM)'	Marlee Smith (b) (4)	08 Feb 2021 13:23:46

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'ONCE'	System	08 Feb 2021 13:23:46

US3722066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 13:23:46

US3722066

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	08 Feb 2021 13:23:48

US3722066

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:15:39
User entered 'I'	System	08 Feb 2021 13:23:48

US3722066

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'No (N)'	Marlee Smith (b) (4)	02 Mar 2021 19:39:11

US3722066

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Marlee Smith (b) (4)	02 Mar 2021 19:39:11

US3722066

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Marlee Smith (b) (4)	02 Mar 2021 19:39:11

US3722066

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	Marlee Smith (b) (4)	02 Mar 2021 19:39:11

US3722066

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	02 Mar 2021 19:39:15

US3722066

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:24
User entered 'I'	System	02 Mar 2021 19:39:15

US3722066

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:51:35

US3722066

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '3 Mar 2021'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:51:35

US3722066

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Clinic (Clinic)'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:51:35

US3722066

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User entered 'OLD57'	System	03 Mar 2021 14:51:35

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '3 Mar 2021'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '09:01'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User entered '3 Mar 2021 09:01'	System	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '98.2' F	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Oral (Oral)'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '83'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User entered 'bpm'	System	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '16'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User entered 'breaths/min'	System	03 Mar 2021 14:52:00

US3722066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '130'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User entered 'mmHg'	System	03 Mar 2021 14:52:00

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '81'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:00

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User entered 'mmHg'	System	03 Mar 2021 14:52:00

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:05

US3722066

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered empty.	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:05

US3722066

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:12

US3722066

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '3 Mar 2021'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:12

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User entered '09:09'	(b) (4) Marlee Smith (b) (4)	03 Mar 2021 14:52:12

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:51
User entered '3 Mar 2021 09:09'	System	03 Mar 2021 14:52:12

US3722066

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:32:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per CDM: Per sponsor review, please consider updating AE term to Covid-19.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 11:27:10
Query 'Per CDM: Per sponsor review, please consider updating AE term to Covid-19.' answered with 'AE term is Positive Covid 19' (Site from DM).	Marlee Smith (b) (4) (b) (4)	05 Jan 2021 20:15:32
User opened query 'Per CDM: Per sponsor review, please consider updating AE term to Covid-19.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:03:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:41
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 19:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:20:20
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:11:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:02:03
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:11:42
Un-reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:49
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	13 Apr 2021 17:10:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:08:48
User entered	System	18 Nov 2020 18:08:44
'USA-US083-2020-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	18 Nov 2020 18:08:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 16:20:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 16:20:51
	(b) (4)	
Data point term sent to Coder	System	03 Mar 2021 16:20:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
Data point term sent to Coder	System	03 Mar 2021 16:18:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
Query 'PV Query: PV Query: Please consider reporting only one SAE of Covid-19 by merging both the events as they are of same grade 3 severity, with hospitalization seriousness criteria and a final outcome for the event.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 23:09:40
User opened query 'PV Query: PV Query: Please consider reporting only one SAE of Covid-19 by merging both the events as they are of same grade 3 severity, with hospitalization seriousness criteria and a final outcome for the event.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 23:07:47
User closed query 'PV Query: Please consider updating the event term to the final diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 21:35:36
Query 'PV Query: Please consider updating the event term to the final diagnosis, when available.' answered with 'This was the final diagnosis. ' (Site from Safety).	Sara Poff (b) (4)	14 Dec 2020 16:36:10
	(b) (4)	
User opened query 'PV Query: Please consider updating the event term to the final diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:31:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'PV Query Urgent: Please confirm - is reported events of a single occurrence or recurrence? If single, please report only 1 event of COVID 19 positive. Please consider merging non-serious and serious details in 1 log line. Please consider deleting the other. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:02:38

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query Urgent: Please confirm - is reported events of a single occurrence or recurrence? If single, please report only 1 event of COVID 19 positive. Please consider merging non-serious and serious details in 1 log line. Please consider deleting the other. ' answered with 'Due to the seriousness of the situation, the AE and SAE have been made separate. ' (Site from Safety).	Sara Poff (b) (4)	19 Nov 2020 15:13:35
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 13:38:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 13:38:59
Data point term sent to Coder	System	19 Nov 2020 13:38:21
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Positive COVID 19' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:37:55
Data point term sent to Coder	System	19 Nov 2020 13:33:15
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
User opened query 'PV Query Urgent: Please confirm - is reported events of a single occurrence or recurrence? If single, please report only 1 event of COVID 19 positive. Please consider merging non-serious and serious details in 1 log line. Please consider deleting the other. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 02:11:36
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:19:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:19:50
Data point term sent to Coder	System	17 Nov 2020 20:18:53
User entered 'COVID-19 Positive'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User closed query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing. Please consider revising the response else clarify.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:36:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 02:36:15
DataPoint Un-verified.	Sara Poff (b) (4)	24 Nov 2020 02:26:57
DataPoint Verified.	(b) (4)	
Query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing. Please consider revising the response else clarify.' answered with 'Subject has been hospitalized due to COVID 19.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:16:38
User opened query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing. Please consider revising the response else clarify.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:16:29
Query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing.' canceled (Site from CRA).	Sara Poff (b) (4)	24 Nov 2020 00:32:08
User opened query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing.' (Site from CRA).	(b) (4)	
Query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:07:15
User opened query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:06:39
User opened query 'Thank you for your previous response however this event would not be consider a solicited adverse reaction as ARs are only evaluated during the 7 day period after dosing.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:06:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Please reconcile as this was outside of AR reporting for 7 days post dosing.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:06:24
Query 'Please reconcile as this was outside of AR reporting for 7 days post dosing.' answered with 'This is a SAE that was reported as directed ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	23 Nov 2020 18:52:03
User opened query 'Please reconcile as this was outside of AR reporting for 7 days post dosing.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:56:00
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:56:11
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:42:45
	(b) (4)	
User entered '11 Nov 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:42:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered '16 Nov 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:37:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
	(b) (4)	
User entered '16 Nov 2020'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
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	17 Nov 2020 20:30:44
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	17 Nov 2020 20:30:44
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).	(b) (4)	17 Nov 2020 20:18:07
User entered '15:30'	System	17 Nov 2020 20:18:07
	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	17 Nov 2020 20:30:44
User entered '16 Nov 2020 15:30'	System	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 19:56:13
User entered 'No (N)' reason for change: Data Entry Error	System	14 Dec 2020 16:38:53
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Sara Poff (b) (4)	14 Dec 2020 16:38:53
DataPoint Verified.	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	Sara Poff (b) (4)	14 Dec 2020 16:38:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	System	14 Dec 2020 16:38:33
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty; reason for change Data Entry Error	System	
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
	System	19 Nov 2020 13:37:55
	Sara Poff (b) (4)	19 Nov 2020 13:37:55
	(b) (4)	
	System	19 Nov 2020 13:33:09
	Sara Poff (b) (4)	19 Nov 2020 13:33:09
	(b) (4)	
	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	12 Apr 2021 17:20:58
User closed query 'Please confirm end date, as end date should be equivalent to when Covid 19 symptoms were no longer present. ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:32:52
DataPoint Un-verified.	Kayla Peay (b) (4)	09 Mar 2021 04:37:30
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4)	09 Mar 2021 04:37:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:02:21
Query 'Please confirm end date, as end date should be equivalent to when Covid 19 symptoms were no longer present. ' answered with 'updaed' (Site from CRA).	Marlee Smith (b) (4)	12 Feb 2021 14:31:16
DataPoint Un-verified.	Marlee Smith (b) (4)	12 Feb 2021 14:31:10
User entered '16 Nov 2020' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:31:10
User opened query 'Please confirm end date, as end date should be equivalent to when Covid 19 symptoms were no longer present. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 21:13:53
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Dec 2020 16:38:33
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	14 Dec 2020 16:38:33
DataPoint Un-verified.	Sara Poff (b) (4)	14 Dec 2020 16:38:33
User entered '27 Nov 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	14 Dec 2020 16:38:33

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Form: Adverse Events (1)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).		14 Dec 2020 16:37:47
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)	25 Nov 2020 19:06:26
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 'The subject is still in the hospital ' (Site from Safety).	Sara Poff (b) (4)	24 Nov 2020 21:03:52
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)	24 Nov 2020 19:27:59
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4)	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 16:23:47
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)	04 Dec 2020 22:34:33
User entered empty.	System	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:37:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:57:55
	(b) (4)	
DataPoint Un-verified.	Kayla Peay (b) (4)	12 Apr 2021 20:00:16
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 20:00:16
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:37:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
	(b) (4)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

Death

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:57
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 20:00:16
User entered '0' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 20:00:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
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)	19 Nov 2020 19:08:37
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'This has been updated upon speaking to the subject.' (Site from System).	Sara Poff (b) (4) (b) (4)	19 Nov 2020 15:12:44
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	19 Nov 2020 15:12:12
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)	19 Nov 2020 14:53:01
User entered '1' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55
User entered '0' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[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 'updated' (Site from System).	Marlee Smith (b) (4)	18 Nov 2020 18:42:49
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	17 Nov 2020 20:18:07
User entered '1'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:58:00
	(b) (4)	
DataPoint Un-verified.	Kayla Peay (b) (4)	12 Apr 2021 20:00:16
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 20:00:16
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
User closed query 'PV Query: Please confirm the hospital admission date, it was reported as 16 Nov 2020 and 17 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:06:33
	(b) (4), (b) (6)	
Query 'PV Query: Please confirm the hospital admission date, it was reported as 16 Nov 2020 and 17 Nov 2020.' answered with 'Admission date is 16 NOV 2020' (Site from Safety).	Sara Poff (b) (4)	24 Nov 2020 21:04:23
	(b) (4)	
User opened query 'PV Query: Please confirm the hospital admission date, it was reported as 16 Nov 2020 and 17 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered '16 Nov 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:37:55
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
	(b) (4)	
User entered '17 Nov 2020'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	14 Apr 2021 13:58:02
DataPoint Un-verified.	Kayla Peay (b) (4)	12 Apr 2021 20:00:16
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 20:00:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:21:16
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:48:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
DataPoint Un-verified.	Sara Poff (b) (4)	14 Dec 2020 16:37:47
User entered '27 Nov 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	14 Dec 2020 16:37:47
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:06:36
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Subject is still in the hospital ' (Site from Safety).	Sara Poff (b) (4)	24 Nov 2020 21:06:22
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:27:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4)	17 Nov 2020 20:18:07

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 13:58:04
DataPoint Un-verified.	Kayla Peay (b) (4)	12 Apr 2021 20:00:16
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 20:00:16
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Nov 2020 15:12:12
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		19 Nov 2020 15:12:12
User entered 'No (N)' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 15:12:12
	(b) (4)	
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:37:55
	(b) (4)	
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Nov 2020 13:33:09
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	17 Nov 2020 20:18:07
User entered 'Unknown (UNK)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:37:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:37:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	02 Feb 2021 17:28:42
User closed query 'PV Query: As the last dose of was given on 28 Aug 2020, please consider updating the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:06:39
Query 'PV Query: As the last dose of was given on 28 Aug 2020, please consider updating the action taken from none to not applicable.' answered with 'Updated and completed ' (Site from Safety).	Sara Poff (b) (4)	24 Nov 2020 21:06:58
DataPoint Un-verified.	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sara Poff (b) (4)	24 Nov 2020 21:06:44
User opened query 'PV Query: As the last dose of was given on 28 Aug 2020, please consider updating the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:27:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:37:55
User entered 'None (NONE)' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:33:09
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
User entered 'None (NONE)'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07

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None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:07:31
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:00:26
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:16:46
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:16:26
User entered '0' reason for change: Data Entry Error	Marlee Smith (b) (4)	03 Mar 2021 21:16:26
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:31:43
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 13:37:55
User entered '1' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:37:55

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EAB) (1725)

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None

Audit	User	Time (GMT)
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 13:33:09
User entered '0' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Nov 2020 20:30:44
User entered '1' reason for change: Data Entry Error	Kayla Peay (b) (4)	17 Nov 2020 20:30:44
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Nov 2020 20:18:07
User entered '0'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:07:36
User closed query 'Per CDM: Please confirm no Concomitant Medication was given for this AE. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:59:25
Query 'Per CDM: Please confirm no Concomitant Medication was given for this AE. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:16:33
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:16:26
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:16:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'Per CDM: Please confirm no Concomitant Medication was given for this AE. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 22:41:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:58:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:16
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	06 Apr 2021 13:03:12
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	06 Apr 2021 13:03:07
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	06 Apr 2021 13:03:07
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 02:11:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
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)	02 Feb 2021 17:30:13
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 'Subject was released from the hospital on 27NOV2020. Medical records have been requested.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 21:35:49
DataPoint Un-verified.	Sara Poff (b) (4)	14 Dec 2020 16:39:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	Sara Poff (b) (4)	14 Dec 2020 16:37:47
DataPoint Verified.	(b) (4)	14 Dec 2020 16:37:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 19:28:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:37:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	System	19 Nov 2020 13:37:55
User opened query 'Data is required. Please complete.' (Site from System).	Sara Poff (b) (4)	19 Nov 2020 13:37:55
	(b) (4)	
	System	19 Nov 2020 13:33:09

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[Outcome](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	19 Nov 2020 13:33:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kayla Peay (b) (4)	17 Nov 2020 20:18:07

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	Kayla Peay (b) (4)	17 Nov 2020 20:18:07
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per DM CLR: Narrative = VOLUME OVERLOAD. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 07:21:37
User closed query 'Per DM CLR: Narrative = DISCHARGED ON 23 NOV 2020. However, this is not the recorded Discharged date above. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:21:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:59:19
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:10:38
Query 'Per DM CLR: Narrative = VOLUME OVERLOAD. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Will add volume overload as AE. ' (Site from DM).	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 20:01:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Narrative for Worsening of COVID 19 has been updated to include labs. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 20:01:22
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 20:00:16

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE RECEIVED AN EMAIL ALERT ON 15NOV2020, STATING THAT THE SUBJECT HAD COVID 19 SYMPTOMS. SUBJECT WAS CALLED ON 16NOV2020 AT 08:49 AND AT THAT TIME HE STATED THEY HAD SOB, FEVER OF UP TO 102.6, CHILLS, AND MUSCLE ACHES. SUBJECT WAS ADVISED TO GO TO ER IN THE EVENT OF AN EMERGENCY. SUBJECT EXPRESSED HE JUST THOUGHT HE HAD PNEUMONIA. PER PROTOCOL, SUBJECT WAS SCHEDULED TO COME TO SITE FOR A CONVALESCENT VISIT. UPON ARRIVING THE SUBJECT STATED THAT THEY HAD RECEIVED THEIR TEST RESULTS BACK AND THAT THEY HAD TESTED POSITIVE FOR COVID 19. HIS O2 WAS 87% AT TIME OF VISIT AND THIS WAS CONFIRMED WITH A SECOND READING. THE SUB I ONSITE CONTACTED THE PI WHO ADVISED EMS TO BE CALLED FOR PATIENT TO GO TO THE ER. AT THAT TIME 911 WAS CALLED AND THE SUBJECT WAS TRANSPORTED TO THE ER. SUBJECT WAS TAKEN TO ST. FRANCES DOWNTOWN PER SUBJECT REQUEST. SITE WILL CONTINUE TO FOLLOW UP WITH SUBJECT AS REQUIRED PER PROTOCOL.' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 20:00:16
User closed query 'midway through Narrative, it indicates hospital admission was 17Nov20. Please confirm if this is correct or should be changed to 16Nov20 as noted in response to hospital admission date above.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:50:39
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:44:57
Query 'midway through Narrative, it indicates hospital admission was 17Nov20. Please confirm if this is correct or should be changed to 16Nov20 as noted in response to hospital admission date above.' answered with 'updatedddd' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	12 Apr 2021 17:26:59

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE RECEIVED AN EMAIL ALERT ON 15NOV2020, STATING THAT THE SUBJECT HAD COVID 19 SYMPTOMS. SUBJECT WAS CALLED ON 16NOV2020 AT 08:49 AND AT THAT TIME HE STATED THEY HAD SOB, FEVER OF UP TO 102.6, CHILLS, AND MUSCLE ACHES. SUBJECT WAS ADVISED TO GO TO ER IN THE EVENT OF AN EMERGENCY. SUBJECT EXPRESSED HE JUST THOUGHT HE HAD PNEUMONIA. PER PROTOCOL, SUBJECT WAS SCHEDULED TO COME TO SITE FOR A CONVALESCENT VISIT. UPON ARRIVING THE SUBJECT STATED THAT THEY HAD RECEIVED THEIR TEST RESULTS BACK AND THAT THEY HAD TESTED POSITIVE FOR COVID 19. HIS O2 WAS 87% AT TIME OF VISIT AND THIS WAS CONFIRMED WITH A SECOND READING. THE SUB I ONSITE CONTACTED THE PI WHO ADVISED EMS TO BE CALLED FOR PATIENT TO GO TO THE ER. AT THAT TIME 911 WAS CALLED AND THE SUBJECT WAS TRANSPORTED TO THE ER. SUBJECT WAS TAKEN TO ST. FRANCES DOWNTOWN PER SUBJECT REQUEST. SITE WILL CONTINUE TO FOLLOW UP WITH SUBJECT AS REQUIRED PER PROTOCOL. SUBJECT CONFIRMED VIA PHONE HE WAS ADMITTED TO HOSPITAL ON 16 NOV 2020. SAE DOCUMENTED IN SOURCE AND SPONSOR NOTIFIED. SITE WILL CONTINUE TO FOLLOW PROGRESS OF PATIENT AND WILL GET A MEDICAL RECORDS RELEASE AS SOON AS POSSIBLE IN ORDER TO GET RECORDS. SUBJECT WAS ADMITTED TO HOSPITAL INITIALLY ON 16 NOV 2020 AND DISCHARGED ON 27 NOV 2020, BUT WORSENERED AFTER SOME TIME AT HOME AND WAS ADMITTED AGAIN ON 19 DEC 2020 AND DISCHARGED ON 24 DEC 2020. PI REVIEWED RECORDS AND HIS IMPRESSION IS THAT THE INITIAL SAE OF	Marlee Smith (b) (4) (b) (4)	12 Apr 2021 17:26:41

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Folder: Adverse Events

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Audit	User	Time (GMT)
POSITIVE FOR COVID 19 HAD NOT RESOLVED, RESULTING IN THE SECOND HOSPITALIZATION. SUBJECT TESTED COVID 19 POSITIVE AGAIN ON 19 DEC 2020. CXR SHOWED VOLUME OVERLOAD.' reason for change: Data Entry Error		
User opened query 'midway through Narrative, it indicates hospital admission was 17Nov20. Please confirm if this is correct or should be changed to 16Nov20 as noted in response to hospital admission date above.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:12:31
Query 'Narrative indicates hospital admission was 17Nov20. Please confirm if this is correct or should be changed to 16Nov20 as noted in response to hospital admission date above.' canceled (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:10:56
User opened query 'Narrative indicates hospital admission was 17Nov20. Please confirm if this is correct or should be changed to 16Nov20 as noted in response to hospital admission date above.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:09:35
Query 'Per DM CLR: Narrative = DISCHARGED ON 23 NOV 2020. However, this is not the recorded Discharged date above. Please review and reconcile data as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:15:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE RECEIVED AN EMAIL ALERT ON 15NOV2020, STATING THAT THE SUBJECT HAD COVID 19 SYMPTOMS. SUBJECT WAS CALLED ON 16NOV2020 AT 08:49 AND AT THAT TIME HE STATED THEY HAD SOB, FEVER OF UP TO 102.6, CHILLS, AND MUSCLE ACHES. SUBJECT WAS ADVISED TO GO TO ER IN THE EVENT OF AN EMERGENCY. SUBJECT EXPRESSED HE JUST THOUGHT HE HAD PNEUMONIA. PER PROTOCOL, SUBJECT WAS SCHEDULED TO COME TO SITE FOR A CONVALESCENT VISIT. UPON ARRIVING THE SUBJECT STATED THAT THEY HAD RECEIVED THEIR TEST RESULTS BACK AND THAT THEY HAD TESTED POSITIVE FOR COVID 19. HIS O2 WAS 87% AT TIME OF VISIT AND THIS WAS CONFIRMED WITH A SECOND READING. THE SUB I ONSITE CONTACTED THE PI WHO ADVISED EMS TO BE CALLED FOR PATIENT TO GO TO THE ER. AT THAT TIME 911 WAS CALLED AND THE SUBJECT WAS TRANSPORTED TO THE ER. SUBJECT WAS TAKEN TO ST. FRANCES DOWNTOWN PER SUBJECT REQUEST. SITE WILL CONTINUE TO FOLLOW UP WITH SUBJECT AS REQUIRED PER PROTOCOL. SUBJECT CONFIRMED VIA PHONE HE WAS ADMITTED TO HOSPITAL ON 17 NOV 2020. SAE DOCUMENTED IN SOURCE AND SPONSOR NOTIFIED. SITE WILL CONTINUE TO FOLLOW PROGRESS OF PATIENT AND WILL GET A MEDICAL RECORDS RELEASE AS SOON AS POSSIBLE IN ORDER TO GET RECORDS. SUBJECT WAS ADMITTED TO HOSPITAL INITIALLY ON 16 NOV 2020 AND DISCHARGED ON 27 NOV 2020, BUT WORSENERED AFTER SOME TIME AT HOME AND WAS ADMITTED AGAIN ON 19 DEC 2020 AND DISCHARGED ON 24 DEC 2020. PI REVIEWED RECORDS AND HIS IMPRESSION IS THAT THE INITIAL SAE OF	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:15:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
POSITIVE FOR COVID 19 HAD NOT RESOLVED, RESULTING IN THE SECOND HOSPITALIZATION. SUBJECT TESTED COVID 19 POSITIVE AGAIN ON 19 DEC 2020. CXR SHOWED VOLUME OVERLOAD.' reason for change: Data Entry Error		
User opened query 'Per DM CLR: Narrative = VOLUME OVERLOAD. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 02:11:49
User opened query 'Per DM CLR: Narrative = DISCHARGED ON 23 NOV 2020. However, this is not the recorded Discharged date above. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 02:11:40
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 00:42:36
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 16:04:03
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'Records have been sent. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 15:58:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:16:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE RECEIVED AN EMAIL ALERT ON 15NOV2020, STATING THAT THE SUBJECT HAD COVID 19 SYMPTOMS. SUBJECT WAS CALLED ON 16NOV2020 AT 08:49 AND AT THAT TIME HE STATED THEY HAD SOB, FEVER OF UP TO 102.6, CHILLS, AND MUSCLE ACHES. SUBJECT WAS ADVISED TO GO TO ER IN THE EVENT OF AN EMERGENCY. SUBJECT EXPRESSED HE JUST THOUGHT HE HAD PNEUMONIA. PER PROTOCOL, SUBJECT WAS SCHEDULED TO COME TO SITE FOR A CONVALESCENT VISIT. UPON ARRIVING THE SUBJECT STATED THAT THEY HAD RECEIVED THEIR TEST RESULTS BACK AND THAT THEY HAD TESTED POSITIVE FOR COVID 19. HIS O2 WAS 87% AT TIME OF VISIT AND THIS WAS CONFIRMED WITH A SECOND READING. THE SUB I ONSITE CONTACTED THE PI WHO ADVISED EMS TO BE CALLED FOR PATIENT TO GO TO THE ER. AT THAT TIME 911 WAS CALLED AND THE SUBJECT WAS TRANSPORTED TO THE ER. SUBJECT WAS TAKEN TO ST. FRANCES DOWNTOWN PER SUBJECT REQUEST. SITE WILL CONTINUE TO FOLLOW UP WITH SUBJECT AS REQUIRED PER PROTOCOL. SUBJECT CONFIRMED VIA PHONE HE WAS ADMITTED TO HOSPITAL ON 17 NOV 2020. SAE DOCUMENTED IN SOURCE AND SPONSOR NOTIFIED. SITE WILL CONTINUE TO FOLLOW PROGRESS OF PATIENT AND WILL GET A MEDICAL RECORDS RELEASE AS SOON AS POSSIBLE IN ORDER TO GET RECORDS. Subject was admitted to hospital initially on 16 NOV 2020 and discharged on 23 NOV 2020, but worsened after some time at home and was admitted again on 19 DEC 2020 and discharged on 24 DEC 2020. PI reviewed records and his impression is that the initial SAE of positive for COVID 19 had not resolved, resulting in the second hospitalization. <br	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 20:16:06

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
/>SUBJECT TESTED COVID 19 POSITIVE AGAIN ON 19 DEC 2020. CXR SHOWED VOLUME OVERLOAD.' reason for change: Data Entry Error		
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Narrative updated to add COVID 19 Test positive on 19 DEC 2020 and CXR..' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 20:12:23
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:37:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE RECEIVED AN EMAIL ALERT ON 15NOV2020, STATING THAT THE SUBJECT HAD COVID 19 SYMPTOMS. SUBJECT WAS CALLED ON 16NOV2020 AT 08:49 AND AT THAT TIME HE STATED THEY HAD SOB, FEVER OF UP TO 102.6, CHILLS, AND MUSCLE ACHES. SUBJECT WAS ADVISED TO GO TO ER IN THE EVENT OF AN EMERGENCY. SUBJECT EXPRESSED HE JUST THOUGHT HE HAD PNEUMONIA. PER PROTOCOL, SUBJECT WAS SCHEDULED TO COME TO SITE FOR A CONVALESCENT VISIT. UPON ARRIVING THE SUBJECT STATED THAT THEY HAD RECEIVED THEIR TEST RESULTS BACK AND THAT THEY HAD TESTED POSITIVE FOR COVID 19. HIS O2 WAS 87% AT TIME OF VISIT AND THIS WAS CONFIRMED WITH A SECOND READING. THE SUB I ONSITE CONTACTED THE PI WHO ADVISED EMS TO BE CALLED FOR PATIENT TO GO TO THE ER. AT THAT TIME 911 WAS CALLED AND THE SUBJECT WAS TRANSPORTED TO THE ER. SUBJECT WAS TAKEN TO ST. FRANCES DOWNTOWN PER SUBJECT REQUEST. SITE WILL CONTINUE TO FOLLOW UP WITH SUBJECT AS REQUIRED PER PROTOCOL. SUBJECT CONFIRMED VIA PHONE HE WAS ADMITTED TO HOSPITAL ON 17 NOV 2020. SAE DOCUMENTED IN SOURCE AND SPONSOR NOTIFIED. SITE WILL CONTINUE TO FOLLOW PROGRESS OF PATIENT AND WILL GET A MEDICAL RECORDS RELEASE AS SOON AS POSSIBLE IN ORDER TO GET RECORDS. Subject tested COVID 19 positive again on 19 DEC 2020. CXR showed volume overload.' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:37:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45

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Form: Adverse Events (1)

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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. ' canceled (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 16:25:56
Query 'PV Query: Please consider updating the event term to the final diagnosis, when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 16:25:16
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 16:25:00
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 21:39:06
User opened query 'PV Query: Please consider updating the event term to the final diagnosis, when available. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:43:50
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 21:36:02
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 21:35:55

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Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Will be added when medical records are received ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:40:50
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with '27NOV2020' (Site from Safety).	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:40:07
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:31:14
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:31:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:30:47
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:30:29
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:30:09

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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:06:59
User closed query 'PV Query: Please complete Covid-19 Assessment symptom log, starting on 11 Nov 2020 when it was reported that symptoms started.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:06:56
User closed query 'PV Query: Please consider reporting only one event of Covid-19 and merging the non-serious and serious events into one event.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:06:53
User closed query 'V Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:06:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:06:47
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)	25 Nov 2020 19:06:44
Query 'PV Query: Please consider reporting only one event of Covid-19 and merging the non-serious and serious events into one event.' answered with 'Completed' (Site from Safety).	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:42:59
Query 'PV Query: Please complete Covid-19 Assessment symptom log, starting on 11 Nov 2020 when it was reported that symptoms started.' answered with 'Completed ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:20:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Subject is still in hospital, will request medical records upon release ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:08:49
Query 'V Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Subject is still in hospital, will request medical records upon release ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:08:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Subject is still in hospital, will request medical records upon release ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:08:20
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 'Subject is still in hospital, will request medical records upon release ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 21:08:16
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:29:06
User opened query 'PV Query: Please complete Covid-19 Assessment symptom log, starting on 11 Nov 2020 when it was reported that symptoms started.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:41

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider reporting only one event of Covid-19 and merging the non-serious and serious events into one event.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:32
User opened query 'V Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:27:30
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:27:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Nov 2020 13:38:21
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Nov 2020 13:38:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE RECEIVED AN EMAIL ALERT ON 15NOV2020, STATING THAT THE SUBJECT HAD COVID 19 SYMPTOMS. SUBJECT WAS CALLED ON 16NOV2020 AT 08:49 AND AT THAT TIME HE STATED THEY HAD SOB, FEVER OF UP TO 102.6, CHILLS, AND MUSCLE ACHES. SUBJECT WAS ADVISED TO GO TO ER IN THE EVENT OF AN EMERGENCY. SUBJECT EXPRESSED HE JUST THOUGHT HE HAD PNEUMONIA. PER PROTOCOL, SUBJECT WAS SCHEDULED TO COME TO SITE FOR A CONVALESCENT VISIT. UPON ARRIVING THE SUBJECT STATED THAT THEY HAD RECEIVED THEIR TEST RESULTS BACK AND THAT THEY HAD TESTED POSITIVE FOR COVID 19. HIS O2 WAS 87% AT TIME OF VISIT AND THIS WAS CONFIRMED WITH A SECOND READING. THE SUB I ONSITE CONTACTED THE PI WHO ADVISED EMS TO BE CALLED FOR PATIENT TO GO TO THE ER. AT THAT TIME 911 WAS CALLED AND THE SUBJECT WAS TRANSPORTED TO THE ER. SUBJECT WAS TAKEN TO ST. FRANCES DOWNTOWN PER SUBJECT REQUEST. SITE WILL CONTINUE TO FOLLOW UP WITH SUBJECT AS REQUIRED PER PROTOCOL. SUBJECT CONFIRMED VIA PHONE HE WAS ADMITTED TO HOSPITAL ON 17 NOV 2020. SAE DOCUMENTED IN SOURCE AND SPONSOR NOTIFIED. SITE WILL CONTINUE TO FOLLOW PROGRESS OF PATIENT AND WILL GET A MEDICAL RECORDS RELEASE AS SOON AS POSSIBLE IN ORDER TO GET RECORDS.' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:38:21
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Nov 2020 13:37:55
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:33:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Site received an email alert on 15NOV2020, stating that the subject had COVID 19 symptoms. Subject was called on 16NOV2020 at 08:49 and at that time he stated they had SOB, fever of up to 102.6, chills, and muscle aches. Subject was advised to go to ER in the event of an emergency. Subject expressed he just thought he had pneumonia. Per protocol, subject was scheduled to come to site for a convalescent visit. Upon arriving the subject stated that they had received their test results back and that they had tested positive for COVID 19. His O2 was 87% at time of visit and this was confirmed with a second reading. The Sub I onsite contacted the PI who advised EMS to be called for patient to go to the ER. At that time 911 was called and the subject was transported to the ER. Subject was taken to St. Frances Downtown per subject request. Site will continue to follow up with subject as required per protocol. Subject confirmed via phone he was admitted to hospital on 17 NOV 2020. SAE documented in source and sponsor notified. Site will continue to follow progress of patient and will get a medical records release as soon as possible in order to get records.'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 20:00:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered '1'	System	17 Nov 2020 20:18:07

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered 'I'	System	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered '0'	System	17 Nov 2020 20:18:07

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:17
	(b) (4), (b) (6)	
User entered	(b) (4), (b) (6)	18 Nov 2020 18:09:11
'USA-US083-2020-mRNA-1273-P301000007'	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'PV Query: PV Query: Please consider reporting only one SAE of Covid-19 by merging both the events as they are of same grade 3 severity, with hospitalization seriousness criteria and a final outcome for the event.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:11:03
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:12:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:12:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:29:33
Query 'PV Query: PV Query: Please consider reporting only one SAE of Covid-19 by merging both the events as they are of same grade 3 severity, with hospitalization seriousness criteria and a final outcome for the event.' answered with 'Other entry for COVID 19 should have been for the AE. This entry for the SAE.' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 20:02:34
Data point term sent to Coder	System	12 Apr 2021 19:51:28
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:51:06
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:51:06
User entered 'Worsening of COVID-19' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:51:06
Data point term sent to Coder	System	12 Apr 2021 19:42:14
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:42:06
Data point term sent to Coder	System	09 Mar 2021 04:26:00
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:25:46
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:20:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:20:46
Data point term sent to Coder	System	03 Mar 2021 16:20:31

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EAB) (1725)

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Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
Data point term sent to Coder	System	03 Mar 2021 16:18:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'PV Query: PV Query: Please consider reporting only one SAE of Covid-19 by merging both the events as they are of same grade 3 severity, with hospitalization seriousness criteria and a final outcome for the event.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 23:12:21
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:31:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:24:54
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 14:36:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 14:36:47
Data point term sent to Coder	System	12 Feb 2021 14:35:53
User entered 'COVID positive' reason for change:	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	12 Feb 2021 14:32:52
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
Data point term sent to Coder	System	25 Nov 2020 03:47:24
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4)	25 Nov 2020 03:45:30
Data point term sent to Coder	System	25 Nov 2020 03:45:23
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:29:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:29:01
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User closed query 'PV Query Urgent: Please confirm - is reported events of a single occurrence or recurrence? If single, please report only 1 event of COVID 19 positive. Please consider merging non-serious and serious details in 1 log line. Please consider deleting the other. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:03:05
Query 'PV Query Urgent: Please confirm - is reported events of a single occurrence or recurrence? If single, please report only 1 event of COVID 19 positive. Please consider merging non-serious and serious details in 1 log line. Please consider deleting the other. ' answered with 'This is the original AE. Subjects AE later turned into a SAE. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	19 Nov 2020 15:11:32
User opened query 'PV Query Urgent: Please confirm - is reported events of a single occurrence or recurrence? If single, please report only 1 event of COVID 19 positive. Please consider merging non-serious and serious details in 1 log line. Please consider deleting the other. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 02:11:24
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:40:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:40:58
Data point term sent to Coder	System	17 Nov 2020 20:40:19
User entered 'COVID-19 Positive'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:39:58

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:32:03
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4)	25 Nov 2020 03:45:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:32:12
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:04
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4)	25 Nov 2020 03:45:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered 'No (N)'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:32:17
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:06
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4)	25 Nov 2020 03:45:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'PV Query: Please confirm the onset date for both the events (worsening of COVID-19 and COVID-19 pneumonia). At present it is noted as 16-Nov-2020. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:09:17
Query 'PV Query: Please confirm the onset date for both the events (worsening of COVID-19 and COVID-19 pneumonia). At present it is noted as 16-Nov-2020. ' answered with 'confirmed' (Site from Safety).	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 13:25:17
User opened query 'PV Query: Please confirm the onset date for both the events (worsening of COVID-19 and COVID-19 pneumonia). At present it is noted as 16-Nov-2020. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:10:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:00:43
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:08
User entered '16 Nov 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:34:56
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:46:48
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:45:52
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:44:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '11 Nov 2020'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:29:50
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
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	12 Feb 2021 14:35:11
User entered empty; reason for change Data Entry Error	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:35:11
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	12 Feb 2021 14:34:56
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:34:56
User entered '15:30' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:34:56
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:46:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:39:58

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	12 Feb 2021 14:35:11
User entered '16 Nov 2020 15:30'	System	12 Feb 2021 14:34:56
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	(b) (4)	25 Nov 2020 03:46:48
User entered empty.	System	17 Nov 2020 20:39:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	12 Apr 2021 21:29:52
User closed query 'Please verify if event is still ongoing or if ended.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:29:49
Query 'Please verify if event is still ongoing or if ended.' answered with 'updated' (Site from CRA).	Kayla Peay (b) (4)	12 Apr 2021 20:02:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Apr 2021 19:51:06
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'Please verify if event is still ongoing or if ended.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 16:33:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4)	25 Nov 2020 03:45:59
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered 'No (N)'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Please verify if event has ended and add end date.' (Site from CRA).	(b) (4)	14 Apr 2021 14:00:35
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:00:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 20:07:03
User entered '24 Dec 2020' reason for change: Data Entry Error	System	12 Apr 2021 20:07:03
Query 'Please verify if event has ended and add end date.' answered with 'updated' (Site from CRA).	Kayla Peay (b) (4)	12 Apr 2021 20:02:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	12 Apr 2021 19:51:06
User entered '24 Dec 20' (non-conformant).	System	12 Apr 2021 19:51:06
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'Please verify if event has ended and add end date.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 16:34:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Marlee Smith (b) (4)	25 Nov 2020 03:46:48
DataPoint Un-verified.	(b) (4)	25 Nov 2020 03:44:38
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
DataPoint Verified.	(b) (4)	24 Nov 2020 02:16:29
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 19:08:45

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Please see comment. This became an SAE.' (Site from System).	Kayla Peay (b) (4)	17 Nov 2020 20:40:19
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	17 Nov 2020 20:39:58
User entered '15 Nov 2020'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58

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Generated On: 10 Jun 2021 09:32:46

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
User entered empty.	System	17 Nov 2020 20:39:58

US3722066

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:34:13
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:16
	(b) (4), (b) (6)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4)	25 Nov 2020 03:46:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:34:17
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:19
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	12 Feb 2021 14:35:42
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	12 Feb 2021 14:34:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4)	25 Nov 2020 03:46:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered 'No (N)'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

Death

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4)	
User entered '0'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered '0'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Apr 2021 19:51:06
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	12 Apr 2021 19:51:06
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:34:26
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	12 Feb 2021 14:35:42
DataPoint Un-verified.	Marlee Smith (b) (4)	12 Feb 2021 14:35:42
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:35:42
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:00:57
DataPoint Un-verified.	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
User entered '16 Nov 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'PV Query: Please confirm if discharge dates for both events are correct as reported.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 00:37:38
Query 'PV Query: Please confirm if discharge dates for both events are correct as reported.' answered with 'per medical records date is 24 DEC' (Site from Safety).	Marlee Smith (b) (4) (b) (4)	14 Apr 2021 14:23:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:01:00
User opened query 'PV Query: Please confirm if discharge dates for both events are correct as reported.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:24:29
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:51:06
User entered '24 Dec 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:51:06
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:46:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:39:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:01:05
	(b) (4)	
DataPoint Un-verified.	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered empty.	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:15:50
DataPoint Un-verified.	Kayla Peay (b) (4)	21 Apr 2021 16:38:20
	(b) (4)	
User entered '8' reason for change: Data Entry Error	Kayla Peay (b) (4)	21 Apr 2021 16:38:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:01:07
DataPoint Un-verified.	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
User entered '10' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered empty.	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered '0'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered '0'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered '0'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Generated On: 10 Jun 2021 09:32:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:01:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4)	25 Nov 2020 03:46:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:01:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:24
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4)	25 Nov 2020 03:46:21
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:01:14
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:34:56
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:46:48
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:46:25
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:44:38
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:44:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered 'None (NONE)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:39:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:01:18
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:25:46
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Mar 2021 21:15:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Feb 2021 14:34:56
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:34:56
User entered '0' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:34:56
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:46:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '1'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:39:58

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:01:19
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint Un-verified.	Marlee Smith (b) (4)	03 Mar 2021 21:15:48
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4)	03 Mar 2021 21:15:48
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 14:01:21
DataPoint Un-verified.	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Apr 2021 19:51:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered '0'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 14:01:26
User closed query 'PV Query: Please provide the final event outcome for Covid positive, 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)	13 Apr 2021 17:11:08
Query 'PV Query: Please provide the final event outcome for Covid positive, 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).	Kayla Peay (b) (4)	12 Apr 2021 20:03:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	12 Apr 2021 19:51:06
Data Entry Error		
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'PV Query: Please provide the final event outcome for Covid positive, 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)	22 Feb 2021 23:14:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 05:25:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Feb 2021 14:34:56
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
	Sara Poff (b) (4)	25 Nov 2020 03:46:48

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'Removed per request. Combined with SAE' (Site from System).	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:46:32
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 03:44:38
DataPoint Un-verified.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:44:38
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:44:38
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	24 Nov 2020 02:16:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kayla Peay (b) (4) (b) (4)	17 Nov 2020 20:39:58

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
	(b) (4), (b) (6)	
User entered empty.	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'PV Query: please provide dates that subject was in ICU, as it was noted in worsening of COVID-19 narrative that he spent 10 days in the ICU ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:16:30
Query 'PV Query: please provide dates that subject was in ICU, as it was noted in worsening of COVID-19 narrative that he spent 10 days in the ICU ' answered with '11-16-2020 to 11-24-2020' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	21 Apr 2021 16:37:42
User opened query 'PV Query: please provide dates that subject was in ICU, as it was noted in worsening of COVID-19 narrative that he spent 10 days in the ICU ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:10:39
User closed query 'PV Query: Please confirm if additional event, Sepsis, should be added as subject was treated for sepsis from 16 Nov to 27 Nov.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:14:37
Query 'PV Query: Please confirm if additional event, Sepsis, should be added as subject was treated for sepsis from 16 Nov to 27 Nov.' answered with 'Sepsis is already entered as an AE.' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	15 Apr 2021 16:42:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:01:47
User opened query 'PV Query: Please confirm if additional event, Sepsis, should be added as subject was treated for sepsis from 16 Nov to 27 Nov.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:19:08
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:11:10

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'RELEVANT LABS TO SAE OF WORSENING COVID-19 • COVID-19 TEST 13 NOV 2020 (PER D/C SUMMARY) – (POSITIVE) • BLOOD CULTURE X 2, NO GROWTH. COMPLETED 16 NOV 2020 • CMP 16 NOV 2020 (NA 122 L, K 3.1 L, CL 85 L, GFR EST NON-AA 54 L, CA 8.2 L, AST 41 H, GLOBULIN 3.8 H, A-G RATIO 1.1 L) • D-DIMER 16 NOV 2020 (0.59 H) • BMP 17 NOV 2020 (NA 127 L, CL 93 L, GLUCOSE 115 H) • BMP 18 NOV 2020 (NA 132 L, CL 97 L, GLUCOSE 131 H, AST 42 H, GLOBULIN 3.9 H, A-G RATIO 1.0 L) • CBC W DIFF 18 NOV 2020 (NEUTROPHILS 81 H) • THYROID PANEL 20 NOV 2020 (TSH 0.096 L) • THYROID PANEL 21 NOV 2020 (T4, FREE 1.6 H) • CORTISOL 21 NOV 2020 (0.8 L) (*MAY BE DUE TO DECADRON/DEXAMETHASONE ADMINISTRATION?) • CBC W DIFF 21 NOV 2020 (WBC 11.5 H/NEUTROPHILS 81/ABS. NEUTROPHILS 9.4 • BMP 21 NOV 2020 (NA 136 H, GLOBULIN 3.8 H, A-G RATIO 0.9 L) • CBC W DIFF 22 NOV 2020 (WBC 13.5 H/NEUTROPHILS 84/ABS. NEUTROPHILS 11.3, PLATELETS 483 H) • BMP 22 NOV 2020 (NA 136 L, GLUCOSA 105 H, GLOBULIN 3.6 H, A-G RATIO 0.9 L) • CBC WITH DIFF 23 NOV 2020 (WBC 13.9 H/NEUTROPHILS 81/ABS. NEUTROPHILS 11.3, PLATELETS 596 H) • BMP 23 NOV 2020 (NA 135 L, K 3.3 L, GLUCOSE 132 H, BUN 24 H) • CBC WITH DIFF 24 NOV 2020 (WBC 13.8 H/NEUTROPHILS 80/ABS. NEUTROPHILS 11.1, PLATELETS 640 H) • BMP 24 NOV 2020 (NA 135 L, K 3.3 L, GLUCOSE 117 H, BUN 32 H) • BMP 25 NOV 2020 (NA 134 L, AGAP 4 L, BUN 29 H) • CBC 25 NOV 2020 (WBC 14.8 H, ABS. NEUTROPHILS 11.9 H, PLATELETS 677 H) • D-DIMER 0.59? NO DATE, MENTIONED IN A/P • BNP 126H 19 DEC 2020 • LACTIC ACID 2.2 H 19 DEC 2020 • CBC W DIFF 19 DEC 2020	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 20:12:14

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
(LYMPHOCYTES 8 L) • CMP 19 DEC 2020 (NA 133 L, GLUCOSE 194 H, GLOBULIN 4.2 H, A-G RATIO 0.8 L) Subject confirmed via phone that he was admitted to hospital on 16 NOV 2020. Upon receipt of records, subject was admitted on 16 Nov 2020 and discharged on 27 NOV 2020 and admitted again on 19 DEC 2020 and discharged on 24 DEC 2020. After review with PI, it was determined SAE did not truly resolve, so this is considered one SAE.' reason for change: Data Entry Error		
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Updated' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 20:04:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	05 Apr 2021 00:10:02
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 23:15:43
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 23:12:08
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 23:12:06
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 23:05:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 23:05:24
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Feb 2021 14:34:56
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
	(b) (4)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	25 Nov 2020 03:44:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:16:29
User entered 'AE of COVID 19 positive reported. Symptoms started 11 Nov 2020. The AE was ended on 15 NOV 2020 as the subject's status declined and an SAE started.'	Kayla Peay (b) (4)	17 Nov 2020 20:39:58
	(b) (4)	

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Form: Adverse Events (2)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered 'I'	System	12 Feb 2021 14:34:56
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	(b) (4)	25 Nov 2020 03:46:48
User entered 'O'	System	17 Nov 2020 20:39:58

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Form: Adverse Events (2)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	25 Nov 2020 03:46:48
User entered '1'	System	17 Nov 2020 20:39:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 19:51:06
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	12 Apr 2021 19:42:06
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:25:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:32:15
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4) (b) (4)	25 Nov 2020 03:46:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:28:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:04
Un-reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:19:37
DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 15:19:37
User entered	(b) (4), (b) (6)	10 Mar 2021 15:19:37
'USA-US083-2020-mRNA-1273-P301000007'		
reason for change: Data Entry Error		
DataPoint activated with code reason code Data	(b) (4), (b) (6)	03 Mar 2021 16:19:38
required.		
DataPoint inactivated with code reason code Data not	(b) (4), (b) (6)	03 Mar 2021 16:17:45
required.		
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:38:02
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:01:52
User entered	System	28 Dec 2020 15:01:46
'USA-US083-2020-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	28 Dec 2020 15:01:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'IQVIA Medical query: Please consider whether the event viral pneumonia could be updated to COVID-19 pneumonia based on the information in the source document noting viral pneumonia due to COVID-19 and treatments for pneumonia due to COVID-19.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:14:19
Query 'IQVIA Medical query: Please consider whether the event viral pneumonia could be updated to COVID-19 pneumonia based on the information in the source document noting viral pneumonia due to COVID-19 and treatments for pneumonia due to COVID-19.' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 02:56:27
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19 pneumonia, LLT: COVID-19 pneumonia - version MedDRA\23.0.	Kayla Peay (b) (4) (b) (4)	15 Apr 2021 20:04:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. Data point term sent to Coder DataPoint Un-verified.	Coder Import (b) (4) (b) (4)	15 Apr 2021 16:48:33
Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	15 Apr 2021 16:47:46 15 Apr 2021 16:47:30
User entered 'COVID-19 PNEUMONIA' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	15 Apr 2021 16:47:30
User opened query 'IQVIA Medical query: Please consider whether the event viral pneumonia could be updated to COVID-19 pneumonia based on the information in the source document noting viral pneumonia due to COVID-19 and treatments for pneumonia due to COVID-19.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:21
	(b) (4), (b) (6)	07 Apr 2021 16:35:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Term is Viral Pneumonia due to Covid 19, but no Illness visit was conducted. If this is thought to be related to the previous Covid-19 infection, please revise the end date. Please add a PD for the missing illness visit.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:33:13
User closed query 'Please confirm this term. It seems that the subject had viral pneumonia due to covid 19 during the last hospitalization on 16Nov. The hospitalization on 19Dec indicates Acute Respiratory Failure with Hypoxia. Please determine if this SAE should be revised and a separate SAE for Pneumonia.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:33:10
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Pneumonia viral, LLT: Viral pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 06:14:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 06:14:54
Query 'Term is Viral Pneumonia due to Covid 19, but no Illness visit was conducted. If this is thought to be related to the previous Covid-19 infection, please revise the end date. Please add a PD for the missing illness visit.' answered with 'Dates updated. Subject was in CV period at this time. No PD to report.' (Site from CRA).	Kayla Peay (b) (4)	09 Mar 2021 06:00:40
Data point term sent to Coder	System	09 Mar 2021 06:00:19
Query 'Please confirm this term. It seems that the subject had viral pneumonia due to covid 19 during the last hospitalization on 16Nov. The hospitalization on 19Dec indicates Acute Respiratory Failure with Hypoxia. Please determine if this SAE should be revised and a separate SAE for Pneumonia.' answered with 'Term updated and dates corrected.' (Site from CRA).	Kayla Peay (b) (4)	09 Mar 2021 05:59:55
User entered 'VIRAL PNEUMONIA' reason for change: Data Entry Error	Kayla Peay (b) (4)	09 Mar 2021 05:59:25
Data point term sent to Coder	System	09 Mar 2021 05:59:18
User entered 'VIRAL PNEUMONIAUp' reason for change: Data Entry Error	Kayla Peay (b) (4)	09 Mar 2021 05:58:57
Data point term sent to Coder	System	09 Mar 2021 05:58:17
DataPoint Un-verified.	Kayla Peay (b) (4)	09 Mar 2021 05:58:15

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Kayla Peay (b) (4)	09 Mar 2021 05:58:15
User entered 'VIRAL PNEUMONIA' reason for change: Data Entry Error	Kayla Peay (b) (4)	09 Mar 2021 05:58:15
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19 pneumonia, LLT: COVID-19 pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	03 Mar 2021 16:20:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Mar 2021 16:20:56
Data point term sent to Coder	System	03 Mar 2021 16:20:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
Data point term sent to Coder	System	03 Mar 2021 16:18:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'Term is Viral Pneumonia due to Covid 19, but no Illness visit was conducted. If this is thought to be related to the previous Covid-19 infection, please revise the end date. Please add a PD for the missing illness visit.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 16:08:46
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:38:05
User opened query 'Please confirm this term. It seems that the subject had viral pneumonia due to covid 19 during the last hospitalization on 16Nov. The hospitalization on 19Dec indicates Acute Respiratory Failure with Hypoxia. Please determine if this SAE should be revised and a separate SAE for Pneumonia. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 19:24:49
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19 pneumonia, LLT: COVID-19 pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	28 Dec 2020 13:17:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Dec 2020 13:17:24

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	23 Dec 2020 20:45:32
User entered 'Viral Pneumonia due to COVID 19'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Yes (Y)'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
User entered 'Yes (Y)'	Sara Poff (b) (4)	23 Dec 2020 20:45:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'PV Query: Please confirm the onset date for both the events (worsening of COVID-19 and COVID-19 pneumonia). At present it is noted as 16-Nov-2020. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:09:48
Query 'PV Query: Please confirm the onset date for both the events (worsening of COVID-19 and COVID-19 pneumonia). At present it is noted as 16-Nov-2020. ' answered with 'confirmed' (Site from Safety).	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 13:26:15
User opened query 'PV Query: Please confirm the onset date for both the events (worsening of COVID-19 and COVID-19 pneumonia). At present it is noted as 16-Nov-2020. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:11:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:44:57
User closed query 'Please confirm start date as symptoms seem to have begun on 14Dec2020' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:33:16
User entered '16 Nov 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:58:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
Query 'Please confirm start date as symptoms seem to have begun on 14Dec2020' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:30:27
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:29:57
User entered '14 Dec 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	12 Feb 2021 14:29:57
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
User opened query 'Please confirm start date as symptoms seem to have begun on 14Dec2020' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 15:51:40
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Dec 2020'	Sara Poff (b) (4) (b) (4)	23 Dec 2020 20:45:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	23 Dec 2020 20:45:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 13:41:29
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:41:29
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 13:41:12
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	23 Dec 2020 20:45:11

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Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 17:23:57
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:06:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 14:14:25
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).	Marlee Smith (b) (4)	20 Jan 2021 13:41:20
	(b) (4)	
User entered '24 Dec 2020' reason for change: Data Entry Error	Marlee Smith (b) (4)	20 Jan 2021 13:41:12
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 20:58:34
User entered empty.	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	23 Dec 2020 20:45:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Yes (Y)'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

Death

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
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)	09 Mar 2021 05:58:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	09 Mar 2021 05:58:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Mar 2021 16:19:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
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)	06 Jan 2021 06:08:37
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 'admission date has been entered as well as ICU changed to no per the subject.' (Site from System).	Sara Poff (b) (4)	23 Dec 2020 20:49:23

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User entered '1'	System	23 Dec 2020 20:45:11
	Sara Poff (b) (4) (b) (4)	23 Dec 2020 20:45:11

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Please verify if date of admission should be Nov or Dec. One of the hospital admissions was 19Dec20 according to medical records. Please reconcile.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:18:01
Query 'Please verify if date of admission should be Nov or Dec. One of the hospital admissions was 19Dec20 according to medical records. Please reconcile.' answered with 'updated' (Site from CRA). User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6) Marlee Smith (b) (4) (b) (4)	08 Apr 2021 16:17:59 07 Apr 2021 18:17:11
User opened query 'Please verify if date of admission should be Nov or Dec. One of the hospital admissions was 19Dec20 according to medical records. Please reconcile.' (Site from CRA). DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:17:05
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:52:00
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:58:15
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:58:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '19 Dec 2020'	Sara Poff (b) (4) (b) (4)	23 Dec 2020 20:45:11

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'PV Query: Please confirm if discharge dates for both events are correct as reported.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 00:38:00
Query 'PV Query: Please confirm if discharge dates for both events are correct as reported.' answered with 'per medical records date is 24 DEC' (Site from Safety).	Marlee Smith (b) (4) (b) (4)	14 Apr 2021 14:23:58
User opened query 'PV Query: Please confirm if discharge dates for both events are correct as reported.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:25:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 17:28:17
User closed query 'Please verify hospital discharge date for viral pneumonia.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:24:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:24:05
Query 'Please verify hospital discharge date for viral pneumonia.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:17:15
User entered '24 Dec 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:17:05
User opened query 'Please verify hospital discharge date for viral pneumonia.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:57:21
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:17:41
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Updated.' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:00:52
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:58:15
User entered '21 Nov 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:58:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13

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EAB) (1725)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 20:57:28
User entered empty.	Sara Poff (b) (4) (b) (4)	23 Dec 2020 20:45:11

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	23 Dec 2020 20:45:33
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		23 Dec 2020 20:45:33
User entered 'No (N)' reason for change: Data Entry Error	Sara Poff (b) (4)	23 Dec 2020 20:45:33
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	
User entered 'Unknown (UNK)'	System	23 Dec 2020 20:45:11
	Sara Poff (b) (4)	
	(b) (4)	23 Dec 2020 20:45:11

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 17:34:45
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 14:14:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Marlee Smith (b) (4)	20 Jan 2021 13:41:38
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4)	
User entered 'Not Related (NOT APPLICABLE)'	Marlee Smith (b) (4)	20 Jan 2021 13:41:12
	(b) (4), (b) (6)	30 Dec 2020 20:59:25
	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:45:39
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 22:09:12
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' answered with 'updated' (Site from Safety).	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:19:25
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:18:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:18:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:48:41
User entered 'Not Applicable (NOT APPLICABLE)'	Sara Poff (b) (4) (b) (4)	23 Dec 2020 20:45:11

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 17:34:45
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 14:14:35
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marlee Smith (b) (4)	20 Jan 2021 13:41:43
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4)	
User entered 'None (NONE)'	Marlee Smith (b) (4)	20 Jan 2021 13:41:12
	(b) (4)	
	(b) (4), (b) (6)	30 Dec 2020 20:56:45
	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:45:32
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:46:28
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:19:29
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:18:59
User entered '0' reason for change: Data Entry Error	Marlee Smith (b) (4)	03 Mar 2021 21:18:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:47:10
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.	(b) (4), (b) (6)	23 Feb 2021 07:46:54
' canceled (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45

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None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:31:54
User entered '1'	Sara Poff (b) (4) (b) (4)	23 Dec 2020 20:45:11

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:02:35
	(b) (4)	
DataPoint Un-verified.	Marlee Smith (b) (4)	03 Mar 2021 21:18:59
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4)	03 Mar 2021 21:18:59
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
	(b) (4)	
User entered '0'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
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).	(b) (4), (b) (6)	02 Feb 2021 17:34:45
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).	(b) (4), (b) (6)	21 Jan 2021 14:14:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Marlee Smith (b) (4)	20 Jan 2021 13:41:47
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)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Marlee Smith (b) (4)	20 Jan 2021 13:41:12
	(b) (4), (b) (6)	30 Dec 2020 20:58:55
	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Sara Poff (b) (4)	23 Dec 2020 20:45:11
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
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) (4), (b) (6)	16 Apr 2021 14:14:25
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:14:23
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 'This information is already included in the narrative.' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	15 Apr 2021 20:05:51
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'All data reported under the other SAE. Same hospitalization - do you want this reported twice?' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	15 Apr 2021 20:05:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:44:57
User closed query 'Per DM CLR: Narrative = ADMITTED INTO THE HOSPITAL ON 19DEC2020. However, this is not the recorded Admission date above. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:51:30
User closed query 'PV Query: As the subject was hospitalized from 16 Nov 2020 to 27 Nov 2020, please consider updating the discharge date for the event of viral pneumonia from 21 Nov 2020 to 27 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:45:49
Query 'PV Query: As the subject was hospitalized from 16 Nov 2020 to 27 Nov 2020, please consider updating the discharge date for the event of viral pneumonia from 21 Nov 2020 to 27 Nov 2020.' answered with 'updated' (Site from Safety).	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:17:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = ADMITTED INTO THE HOSPITAL ON 19DEC2020. However, this is not the recorded Admission date above. Please review and reconcile data as appropriate. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	07 Apr 2021 18:17:21
User opened query 'Per DM CLR: Narrative = ADMITTED INTO THE HOSPITAL ON 19DEC2020. However, this is not the recorded Admission date above. Please review and reconcile data as appropriate.'	(b) (4)	
(Site from DM).		
User opened query 'PV Query: As the subject was hospitalized from 16 Nov 2020 to 27 Nov 2020, please consider updating the discharge date for the event of viral pneumonia from 21 Nov 2020 to 27 Nov 2020.'	(b) (4), (b) (6)	27 Mar 2021 02:12:31
(Site from Safety).		
User closed query 'PV Query: please provide dates for concomitant medication azithromycin and confirm if this was considered treatment or not.'	(b) (4), (b) (6)	19 Mar 2021 14:35:37
(Site from Safety).		
User closed query 'PV Query: please provide dates for concomitant medication azithromycin and confirm if this was considered treatment or not.'	(b) (4), (b) (6)	15 Mar 2021 15:00:54
(Site from Safety).		
Query 'PV Query: please provide dates for concomitant medication azithromycin and confirm if this was considered treatment or not.'	Marlee Smith (b) (4)	12 Mar 2021 14:53:47
answered with 'confirmed and updated' (Site from Safety).	(b) (4)	
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.'	(b) (4), (b) (6)	12 Mar 2021 00:42:52
(Site from Safety).		
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.'	(b) (4), (b) (6)	11 Mar 2021 14:25:34
(Site from Safety).		
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.'	(b) (4), (b) (6)	11 Mar 2021 14:25:01
(Site from Safety).		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: please provide dates for concomitant medication azithromycin and confirm if this was considered treatment or not.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:24:49
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records have been sent. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 15:58:32
User closed query 'PV Query: please provide dates for concomitant medication azithromycin and confirm if this was considered treatment or not.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:18:17
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:17:59
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:17:48
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)	10 Mar 2021 15:17:31
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Con Meds entered.' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 21:02:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'COVID 19 test provided in narrative. ' (Site from Safety).	Kayla Peay (b) (4)	09 Mar 2021 21:00:11
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID 19 positive test from 11-13-2020 included in narrative. ' (Site from Safety).	Kayla Peay (b) (4)	09 Mar 2021 20:59:39
DataPoint Un-verified.	Kayla Peay (b) (4)	09 Mar 2021 20:58:59
User entered 'SUBJECT CALLED THE SITE AND INFORMED US THAT HE WAS BACK IN THE HOSPITAL DUE TO VIRAL PNEUMONIA DUE TO COVID 19. SUBJECT REPORTED THAT HE WAS ADMITTED INTO THE HOSPITAL ON 19DEC2020. SITE WILL REQUEST MEDICAL RECORDS FROM THE SUBJECT.	Kayla Peay (b) (4)	09 Mar 2021 20:58:59
Upon receipt of medical records, the report from the patient was not accurate. Site has update SAEs to reflect the records.		
COVID 19 positive test on 11/13/2020' reason for change: Data Entry Error		
Query 'PV Query: please provide dates for concomitant medication azithromycin and confirm if this was considered treatment or not.' answered with 'Records state azithromycin given, but do not provide further details' (Site from Safety).	Kayla Peay (b) (4)	09 Mar 2021 05:57:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'PV Query: please provide dates for concomitant medication azithromycin and confirm if this was considered treatment or not.' (Site from Safety).	(b) (4), (b) (6)	21 Feb 2021 18:04:12
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:52:13

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 20:59:08
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 20:58:45
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 20:58:16
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).	(b) (4), (b) (6)	30 Dec 2020 20:57:18
User entered 'Subject called the site and informed us that he was back in the hospital due to viral pneumonia due to COVID 19. Subject reported that he was admitted into the hospital on 19DEC2020. Site will request medical records from the subject.'	Sara Poff (b) (4) (b) (4)	23 Dec 2020 20:45:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered 'I'	System	23 Dec 2020 20:45:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered 'I'	System	23 Dec 2020 20:45:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered '0'	System	23 Dec 2020 20:45:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety reaction - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 16:35:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 16:35:42
Data point term sent to Coder	System	03 Mar 2021 16:20:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
Data point term sent to Coder	System	03 Mar 2021 16:18:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety reaction - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 15:39:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 15:39:02
Data point term sent to Coder	System	20 Jan 2021 13:37:55
User entered 'anxiety secondary to COVID 19'	Marlee Smith (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:27:58
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:07:51
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 17:08:47
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 17:08:41
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 17:08:41
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:24:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'None (NONE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 03:17:44
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 03:17:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'I'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:37:39

US3722066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered '0'	System	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered '1'	System	20 Jan 2021 13:37:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:21:41
Data point term sent to Coder	System	03 Mar 2021 16:20:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
Data point term sent to Coder	System	03 Mar 2021 16:18:28
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:40:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:40:03
Data point term sent to Coder	System	20 Jan 2021 13:38:56
User entered 'Hypokalemia'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

US3722066

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'None (NONE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 21:38:53
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Updated entry to con med procedure' (Site from DM).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:59:55
User entered '0' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:59:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:48:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '1'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered '1' reason for change: Data Entry Error	Kayla Peay (b) (4)	09 Mar 2021 04:59:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:38:41

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Form: Adverse Events (5)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered '0'	System	20 Jan 2021 13:38:41

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered '1'	System	20 Jan 2021 13:38:41

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:21:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:21:42
Data point term sent to Coder	System	03 Mar 2021 16:20:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
Data point term sent to Coder	System	03 Mar 2021 16:18:28
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:55:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:55:03
Data point term sent to Coder	System	20 Jan 2021 13:39:57
User entered 'sepsis'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered empty.	System	20 Jan 2021 13:39:33

US3722066

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

US3722066

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

US3722066

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

US3722066

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

US3722066

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'None (NONE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:00:51
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Updated Con Meds' (Site from DM).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:20:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:49:37
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'I'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:34:45
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered '0'	System	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45
User entered '1'	System	20 Jan 2021 13:39:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 16:19:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Mar 2021 16:17:45

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 05:51:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 05:51:51
Data point term sent to Coder	System	09 Mar 2021 05:51:16
User entered 'Hyponatremia'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered 'Yes (Y)'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered 'No (N)'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:32:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered 'No (N)'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered '16 Nov 2020'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User entered empty.	System	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered 'No (N)'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Please verify stop date. Does not match treatment date.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:20:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:20:17
Query 'Please verify stop date. Does not match treatment date.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:34
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:29
User entered '19 Nov 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:29
User opened query 'Please verify stop date. Does not match treatment date.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:46:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered '24 Dec 2020'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User entered empty.	System	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:36:16
User entered 'No (N)'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:51
User entered '0'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:49
User entered '0'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:47
User entered '0'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:45
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:41
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:39
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:34
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:31
User entered '0'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:28
User entered '0'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:43:20
User entered '0'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:42:26
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:42:24
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:42:22
User entered 'None (NONE)'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:42:11
User entered '0'	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:44:57
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:49:20
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 13:49:10
User entered '0' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 13:49:00
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Mar 2021 02:12:43
User entered '1'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:34:43
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:42:01
Query 'Hyperglycemia correction is not an expected con-procedure for hypnoatremia.' canceled (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:41:53
User opened query 'Hyperglycemia correction is not an expected con-procedure for hypnoatremia.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:34:48
Query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' answered with 'hyperglycemia correction' (Site from DM).	Marlee Smith (b) (4) (b) (4)	12 Apr 2021 17:24:56
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 03:19:26
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4)	30 Mar 2021 13:49:00
User entered '0'	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:48:58

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:38:18

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:34:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:38:18

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:34:58
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:00
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	(b) (4) Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User entered '0'	System	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
User entered '1'	System	09 Mar 2021 05:50:37
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:29
DataPoint activated with code reason code Data required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:48:58
DataPoint inactivated with code reason code Data not required.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 04:38:18

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Folder: Adverse Events

Form: Adverse Events (8)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Total fluid volume increased, PT: Fluid overload, LLT: Volume overload - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:56:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:56:28
Data point term sent to Coder	System	13 Apr 2021 17:23:41
User entered 'Volume overload'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '19 Dec 2020'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User entered empty.	System	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '24 Dec 2020'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User entered empty.	System	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

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Folder: Adverse Events

Form: Adverse Events (8)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'l'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:58:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User entered '0'	System	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34
User entered 'I'	System	13 Apr 2021 17:23:07

US3722066

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:24:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:32:46

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per ETRTR: Please confirm no medication was dosed at hospitalization for COVID-19. If medication was dosed, please state so within COVID-19 AE page and add Concomitant Medications details in this folder, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:31:59
Query 'Per ETRTR: Please confirm no medication was dosed at hospitalization for COVID-19. If medication was dosed, please state so within COVID-19 AE page and add Concomitant Medications details in this folder, thanks.' answered with 'medication has been entered' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 15:40:43
User opened query 'Per ETRTR: Please confirm no medication was dosed at hospitalization for COVID-19. If medication was dosed, please state so within COVID-19 AE page and add Concomitant Medications details in this folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 21:00:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:39:27
User closed query 'Per CDM : In Diary Dose 1 - Temperature Day 11,12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:32:09
Query 'Per CDM : In Diary Dose 1 - Temperature Day 11,12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' answered with 'According to source, subject was taking Tylenol for arthritis and not for vaccine. Conmed was added to conmeds as such. Arthritis is in MH ' (Site from DM).	Sara Poff (b) (4) (b) (4)	22 Oct 2020 22:28:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:32:46

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per CDM : In Diary Dose 1 - Temperature Day 11,12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 06:40:33
Query 'Per CDM : In Diary Dose 1 - Temperature Day 12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' canceled (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 06:40:18
User opened query 'Per CDM : In Diary Dose 1 - Temperature Day 12,13,14,15 & 16 , Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 13:22:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 15:02:12
User entered 'No (N)'	Kayla Peay (b) (4)	06 Aug 2020 13:00:00

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:13
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:20 12 Aug 2020 20:24:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:04:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:04:09
Data point term sent to Coder User entered 'amlodipine besylate'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:06 11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per CDM : In Diary Dose 1 - Temperature Day 11, Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:39:00
Query 'Per CDM : In Diary Dose 1 - Temperature Day 11, Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' answered with 'SUBJECT ALREADY TAKING TYLENOL FOR MEDICAL HISTORY OF ARTHRITIS. NOT TAKEN FOR SOLICITED REACTION OF INJECTION' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:23:20
User opened query 'Per CDM : In Diary Dose 1 - Temperature Day 11, Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 12:19:03
User entered 'hypertension' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:24:40
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '10'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:38:47
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	11 Aug 2020 15:03:02
User entered 'un UNK 2005'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:03:02

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:14
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4)	12 Aug 2020 20:25:20 12 Aug 2020 20:24:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 22:09:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:09:13
Data point term sent to Coder User entered 'atorvastatin'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:08 11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered 'hypercholesterolemia' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:24:56
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered '20'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:38:52
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	11 Aug 2020 15:03:45
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:49
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:03:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:26:13
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:21 12 Aug 2020 20:25:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:06:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:06:11
Data point term sent to Coder User entered 'gabapentin'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:09 11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'restless leg syndrome' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:08
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '1500'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:38:58
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	11 Aug 2020 15:04:32
User entered 'un Jul 2016'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:04:32

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: INDAPAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:57:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:57:18
Data point term sent to Coder	System	12 Aug 2020 20:25:20
Data point term sent to Coder	System	11 Aug 2020 15:06:14
User entered 'indapamide'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'hypertension' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:17
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '1.25'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:39:03
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	11 Aug 2020 15:05:31
User entered 'un UNK 2019'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:05:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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) (b) (4)	12 Aug 2020 20:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:24 12 Aug 2020 20:25:30
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) (b) (4)	11 Aug 2020 15:08:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:08:09
Data point term sent to Coder User entered 'levothyroxine'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:16 11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'hypothyroidism' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:30
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '.112'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:39:07
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	11 Aug 2020 15:06:16
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:06:16

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:22 12 Aug 2020 20:25:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:13:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:13:07
Data point term sent to Coder User entered 'omeprazole'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:22 11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:28:11
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'GERD' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:39
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '20'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:39:11
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	11 Aug 2020 15:07:36
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:07:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
Data point term sent to Coder	System	12 Aug 2020 20:26:21
Data point term sent to Coder	System	11 Aug 2020 15:08:23
User entered 'ropinirole'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Restless leg syndrome' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:25:53
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '2'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:11
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	11 Aug 2020 15:08:17
User entered 'un UNK 2015'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:08:17

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:27:10
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:22 12 Aug 2020 20:26:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:59:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:59:07
Data point term sent to Coder User entered 'valsartan'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:28 11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'hypertension' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:04
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '320'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:16
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	11 Aug 2020 15:08:57
User entered 'un UNK 2016'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:08:57

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:42:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:42:17
Data point term sent to Coder	System	12 Aug 2020 20:26:25
Data point term sent to Coder	System	11 Aug 2020 15:10:31
User entered 'Flovent'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'asthma' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:22
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '100'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'ug (ug)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:20
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	11 Aug 2020 15:09:38
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:09:38

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:13:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:13:54
User closed query 'Per DM CLR: Please review the strength recorded in the medication name as this is not the standard strength for this medication. Please provide the appropriate drug strength.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 16:45:28
Query 'Per DM CLR: Please review the strength recorded in the medication name as this is not the standard strength for this medication. Please provide the appropriate drug strength.' answered with 'updated' (Site from DM).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 20:53:18
Data point term sent to Coder	System	09 Mar 2021 20:52:50
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 20:52:22
User entered 'IPRATROPIUM' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 20:52:22
User opened query 'Per DM CLR: Please review the strength recorded in the medication name as this is not the standard strength for this medication. Please provide the appropriate drug strength.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:04:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:17:35

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:17:35
	System	21 Oct 2020 17:26:37
	Amy Ford (b) (4)	21 Oct 2020 17:25:39
	(b) (4)	
User entered 'IPRATROPIUM .006%' reason for change: Data Entry Error	Amy Ford (b) (4)	21 Oct 2020 17:25:39
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:07:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:07:48
	System	25 Sep 2020 13:18:00
	Amy Ford (b) (4)	25 Sep 2020 13:17:59
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:47:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder Data point term sent to Coder User entered 'ipratropium'	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:47:12
	System	12 Aug 2020 20:27:26
	System	11 Aug 2020 15:11:33
	Kayla Peay (b) (4)	11 Aug 2020 15:11:09
	(b) (4)	

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Please note that there is no MH 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)	10 Mar 2021 13:59:14
Query 'Per DM CLR: Please note that there is no MH Marlee Smith 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' (Site from DM).	(b) (4) (b) (4)	09 Mar 2021 15:29:06
User opened query 'Per DM CLR: Please note that there is no MH 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)	10 Dec 2020 09:46:21
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.'	(b) (4), (b) (6)	10 Dec 2020 09:45:43
' canceled (Site from DM).		
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.'	(b) (4), (b) (6)	10 Dec 2020 09:43:41
' (Site from DM).		
User entered 'rhinorrhea' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:26:37
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '100' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 20:52:22
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:24:38
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Amy Ford (b) (4) (b) (4)	27 Oct 2020 14:58:37
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 03:25:32
User closed query 'Per DM CLR: Note 0.006% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Ipratropium 0.006%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Spray). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:19:25
Query 'Per DM CLR: Note 0.006% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Ipratropium 0.006%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Spray). Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:48
User entered '2' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:39
User opened query 'Per DM CLR: Note 0.006% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Ipratropium 0.006%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Spray). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:33:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '.006'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'ug (ug)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 20:52:22
User entered 'Other (OTHER)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	27 Oct 2020 14:58:20
User closed query 'Per DM CLR: Please review "Other Route" as there is an available option for "Nasal" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:41:09
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	21 Oct 2020 17:27:33
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Nasal" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'UPDATED' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:27:08
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:27:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 17:27:00
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	21 Oct 2020 17:27:00
User entered 'ug (ug)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:27:00
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:26:45
User entered empty; reason for change Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:26:45
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Nasal" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:34:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 20:52:22
User entered 'sprays each nostril' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	27 Oct 2020 14:58:20
User entered empty; reason for change Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:27:33
User entered 'SPRAYS EACH NOSTRIL' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:39
User entered 'per cent'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'twice daily (BID)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	21 Jan 2021 14:50:35
User entered 'once daily (QD)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:25:39
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 20:52:22
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:17:59
User entered 'Other (OTHER)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per CDM: Please note that "Nasal" is an available option for route of administration. Kindly consider to update Route of Administration field as appropriate and remove "2 SPRAYS EACH NOSTRIL" in If route of administration is Other, specify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:26:44
Query 'Per CDM: Please note that "Nasal" is an available option for route of administration. Kindly consider to update Route of Administration field as appropriate and remove "2 SPRAYS EACH NOSTRIL" in If route of administration is Other, specify.' answered with 'updated' (Site from DM).	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:18:06
User entered empty; reason for change Data Entry Error	Amy Ford (b) (4) (b) (4)	25 Sep 2020 13:17:59
User opened query 'Per CDM: Please note that "Nasal" is an available option for route of administration. Kindly consider to update Route of Administration field as appropriate and remove "2 SPRAYS EACH NOSTRIL" in If route of administration is Other, specify.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 08:45:28
User entered '2 sprays each nostril'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:25
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	11 Aug 2020 15:11:09
User entered 'un UNK 2019'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Jan 2021 14:50:35
User entered '1'	System	21 Oct 2020 17:25:39
User entered '2'	System	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:11:09

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:28 12 Aug 2020 20:26:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:13:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:13:14
Data point term sent to Coder User entered 'montelukast'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:34 11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'seasonal allergies' reason for change:	Kayla Peay (b) (4)	12 Aug 2020 20:26:48
Data Entry Error	(b) (4)	
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '10'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:29
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	11 Aug 2020 15:11:53
User entered 'un UNK 1990'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:11:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:28 12 Aug 2020 20:27:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:15:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:15:12
Data point term sent to Coder User entered 'aspirin'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:37 11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'cardiac prophylaxis' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:04
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '81'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:34
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	11 Aug 2020 15:12:45
User entered 'un UNK 2010'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:12:45

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:28:12
Data point term sent to Coder	System	12 Aug 2020 20:27:28
Data point term sent to Coder	System	11 Aug 2020 15:13:39
User entered 'ferrous sulfate'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:44:27
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 17:29:07
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:50:53
User entered 'iron deficiency anemia' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:22
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '130'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:38
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	11 Aug 2020 15:13:27
User entered 'un UNK 1995'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:13:27

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:29:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:29:14
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:28:29 12 Aug 2020 20:27:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:17:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:17:09
Data point term sent to Coder User entered 'tylenol ER'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:45 11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'osteoarthritis' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:42
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '650'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:42
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	11 Aug 2020 15:15:01
User entered 'un UNK 2018'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:15:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 19:27:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 19:27:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: CO Q10 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:29:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:29:13
Data point term sent to Coder	System	12 Aug 2020 20:28:29
Coding entries removed.	Kayla Peay (b) (4)	12 Aug 2020 20:27:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: CO Q10 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:06:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:06:12
Data point term sent to Coder	System	11 Aug 2020 15:15:46
User entered 'co-q10'	Kayla Peay (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered 'supplement' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:51
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered '100'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:55
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	11 Aug 2020 15:15:39
User entered 'un UNK 2018'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:43
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:18
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:15:39

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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) (b) (4)	12 Aug 2020 20:29:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:29:13
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:28:29 12 Aug 2020 20:27:59
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) (b) (4)	11 Aug 2020 15:17:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:17:11
Data point term sent to Coder User entered 'vitamin d3'	System Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:47 11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'supplement' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 20:27:59
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '1000'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'IU (IU)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:40:59
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	11 Aug 2020 15:16:21
User entered 'un UNK 2014'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:16:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 21:13:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 21:13:46
Data point term sent to Coder Coding entries removed.	System Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:12:59 03 Mar 2021 21:12:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 16:43:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 16:43:55
Data point term sent to Coder User entered 'Mucinex'	System Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:55 14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:01:50
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:12:50
User entered 'FOR NASAL AND CHEST CONGESTION due to COVID 19' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:12:43
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 06:29:15
User entered 'For nasal and chest congestion'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Please verify dose, as it is noted in Medical Records as 1,200mg BID. Perhaps there was a dose change?' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:23:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
Query 'Please verify dose, as it is noted in Medical Records as 1,200mg BID. Perhaps there was a dose change?' answered with 'Dose corrected entry error' (Site from CRA).	Sara Poff (b) (4) (b) (4)	07 Apr 2021 17:34:45
User entered '1,200' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	07 Apr 2021 17:34:00
User opened query 'Please verify dose, as it is noted in Medical Records as 1,200mg BID. Perhaps there was a dose change?' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:20:45
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:19:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered '150'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered 'mg (mg)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered empty.	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered 'twice daily (BID)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered empty.	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered 'Oral (ORAL)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered empty.	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered '0'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered empty.	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:19:31
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 16:42:14

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 07:20:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 07:20:59
Data point term sent to Coder	System	09 Mar 2021 21:16:10
Coding entries removed.	Kayla Peay (b) (4)	09 Mar 2021 21:16:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:36:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 16:44:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 16:44:58
Data point term sent to Coder	System	14 Dec 2020 16:43:55
User entered 'Lexapro'	Sara Poff (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:23:18
User closed query 'Per medical records received from in-patient hospitalization, subject was agitated AE due to Covid19 and therefore was started on lexapro. Please consider revising this term. There are conflicting notes if patient is still on this. Please ensure to confirm with patient if this is still ongoing. ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:33:42
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 08:37:54
DataPoint Un-verified.	Kayla Peay (b) (4)	09 Mar 2021 21:16:00
User entered 'Anxiety secondary to COVID 19' reason for change: Data Entry Error	(b) (4)	
Query 'Per medical records received from in-patient hospitalization, subject was agitated AE due to Covid19 and therefore was started on lexapro. Please consider revising this term. There are conflicting notes if patient is still on this. Please ensure to confirm with patient if this is still ongoing. ' answered with 'Confirmed data entered is correct. ' (Site from CRA).	Kayla Peay (b) (4)	09 Mar 2021 21:16:00
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'AEs updated to reflect depression.' (Site from DM).	Kayla Peay (b) (4)	09 Mar 2021 21:14:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 21:14:43
	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:36:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per medical records received from in-patient hospitalization, subject was agitated AE due to Covid19 and therefore was started on lexapro. Please consider revising this term. There are conflicting notes if patient is still on this. Please ensure to confirm with patient if this is still ongoing.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 20:36:17
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:55:44
Query 'per CDM: depression not listed on MH form, please clarify or reconcile' canceled (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 19:28:04
User opened query 'per CDM: depression not listed on MH form, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:06:06
User entered 'Depression'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered '10'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered 'mg (mg)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered empty.	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered 'once daily (QD)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered empty.	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered 'Oral (ORAL)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered empty.	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered '16 Nov 2020'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered '0'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 19:01:49
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	06 Apr 2021 13:15:24
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	06 Apr 2021 13:15:19
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	06 Apr 2021 13:15:19
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 03:18:07
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	Marlee Smith (b) (4)	06 Apr 2021 13:15:19
User entered '27 Nov 2020' reason for change: Data Entry Error	(b) (4) Marlee Smith (b) (4)	06 Apr 2021 13:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered empty.	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:36:34
User entered 'No (N)'	Sara Poff (b) (4) (b) (4)	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User entered '1'	System	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User entered '1'	System	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:45:12
User entered '804 (804)'	System	14 Dec 2020 16:43:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:12:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:12:03
Data point term sent to Coder	System	20 Jan 2021 13:11:26
User entered 'Gabapentin'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'restless leg syndrom'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '600'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '03 Aug 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 13:10:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'During the November hospitalization, subject received 1000 mg of Vitamin C 3 times a day, oral per medical records, if confirmed, please update.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:11:28
Query 'During the November hospitalization, subject received 1000 mg of Vitamin C 3 times a day, oral per medical records, if confirmed, please update.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:39:31
User opened query 'During the November hospitalization, subject received 1000 mg of Vitamin C 3 times a day, oral per medical records, if confirmed, please update.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 20:50:37
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:27
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:13:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:13:06
Data point term sent to Coder	System	20 Jan 2021 13:12:26
User entered 'oxygen'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per DM CLR: Please review AE eCRF's AE #1 COVID-19 (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 12:36:50
Query 'Per DM CLR: Please review AE eCRF's AE #1 COVID-19 (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:14:03
User opened query 'Per DM CLR: Please review AE eCRF's AE #1 COVID-19 (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:05:02
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered 'COVID-19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered '13'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered 'liter'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:21:55
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:01:25
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:01:18
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 21:01:18
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:05:07
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:03:27
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User entered empty.	System	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User entered empty.	System	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:28
User entered empty.	System	20 Jan 2021 13:11:49

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:11:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:11:13
Data point term sent to Coder	System	20 Jan 2021 13:14:30
User entered 'lasix'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered 'AE of COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered '20'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:10:58
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:37:14
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:10
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:05
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:05:18
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User entered '1'	System	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User entered '1'	System	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:35
User entered '804 (804)'	System	20 Jan 2021 13:13:48

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per Medical Records, subject received Convalescent Plasma on 20Dec20. Please update Con-Meds.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:13:14
Query 'Per Medical Records, subject received Convalescent Plasma on 20Dec20. Please update Con-Meds.' answered with 'Receiving blood / plasma is a con procedure. It is listed in the subjects procedures.' (Site from CRA).	Sara Poff (b) (4) (b) (4)	07 Apr 2021 19:00:09
User opened query 'Per Medical Records, subject received Convalescent Plasma on 20Dec20. Please update Con-Meds.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:19:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:18:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:56:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:56:03
Data point term sent to Coder	System	20 Jan 2021 13:15:31
User entered 'albuterol'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered '90'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered 'ug (ug)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:18:37
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:41:35
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:26
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:18
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:05:29
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User entered empty.	System	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User entered empty.	System	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:36:39
User entered empty.	System	20 Jan 2021 13:14:30

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:57:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:57:03
Data point term sent to Coder	System	20 Jan 2021 13:15:30
User entered 'lorazepam'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered 'Anxiety related to covid 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered '0.5'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:03
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:41:41
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:38
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:32
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:05:45
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User entered empty.	System	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User entered empty.	System	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:28
User entered empty.	System	20 Jan 2021 13:15:19

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROTIGOTINE, PRODUCTSYNONYM: NEUPRO - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:17:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:17:03
Data point term sent to Coder	System	20 Jan 2021 13:16:31
User entered 'neupro'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered 'restless leg syndrome'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered '4/24'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered 'Transdermal (TRANSDERMAL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:29:58
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:41:47
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:49
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:44
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:05:58
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User entered '1'	System	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User entered '1'	System	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:35
User entered '804 (804)'	System	20 Jan 2021 13:16:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Apr 2021 13:51:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:51:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:47:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:47:51
Data point term sent to Coder Coding entries removed.	System Marlee Smith (b) (4) (b) (4)	12 Apr 2021 17:22:45 12 Apr 2021 17:22:44
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:05:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:03:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:03:03
Data point term sent to Coder User entered 'sodium chloride'	System Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:32 20 Jan 2021 13:16:59

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	Marlee Smith (b) (4)	12 Apr 2021 17:22:44
User entered 'Hyponatremia' reason for change:	(b) (4)	
Data Entry Error	Marlee Smith (b) (4)	12 Apr 2021 17:22:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered 'COVID 19'	Marlee Smith (b) (4)	20 Jan 2021 13:16:59
	(b) (4)	

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered '5-40'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered 'mL (mL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered 'Q8H'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered 'IV'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:25:26
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:41:52
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:59
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:54
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:49:54
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:06:08
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:05:03
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User entered empty.	System	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User entered empty.	System	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:43
User entered empty.	System	20 Jan 2021 13:16:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Apr 2021 14:04:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:04:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
Query 'Is this a duplicate entry? The only difference is that this entry notes frequency "as needed" and the other indicates frequency as "Q8H". Please confirm if these can be combined.' canceled (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:34:05
User opened query 'Is this a duplicate entry? The only difference is that this entry notes frequency "as needed" and the other indicates frequency as "Q8H". Please confirm if these can be combined.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:29:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:03:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:03:04
Data point term sent to Coder	System	20 Jan 2021 13:18:32
User entered 'sodium chloride'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '5-40'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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)	08 Mar 2021 14:08:43
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 17:24:36
User entered 'mL (mL)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 17:24:04
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)	17 Feb 2021 12:06:22
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'IV'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:42:00
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:50:27
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:50:07
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:06:34
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User entered empty.	System	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User entered empty.	System	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:37:47
User entered empty.	System	20 Jan 2021 13:17:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:20:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:20:12
Data point term sent to Coder	System	20 Jan 2021 13:19:42
User entered 'acetaminophen'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered '650'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered 'Q6h PRN'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:10
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:42:07
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:50:56
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:50:49
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:06:46
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User entered empty.	System	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User entered empty.	System	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:50
User entered empty.	System	20 Jan 2021 13:18:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:20:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:20:10
Data point term sent to Coder	System	20 Jan 2021 13:19:33
User entered 'acetaminophen'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '650'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'suppository'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:42:22
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:08
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:03
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:06:55
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User entered empty.	System	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User entered empty.	System	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:53
User entered empty.	System	20 Jan 2021 13:19:21

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:21:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:21:13
Data point term sent to Coder	System	20 Jan 2021 13:20:43
User entered 'miralax'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered '17'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered 'g (g)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:35:27
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:42:33
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:19
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:14
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:07:05
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User entered empty.	System	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User entered empty.	System	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:39:58
User entered empty.	System	20 Jan 2021 13:19:58

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PHENOTHIAZINE DERIVATIVES, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:02:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:02:04
Data point term sent to Coder	System	20 Jan 2021 13:21:44
User entered 'Phenergan'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '12.5'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Q6H PRN'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:42:45
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:32
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:26
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:07:14
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User entered empty.	System	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User entered empty.	System	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:03
User entered empty.	System	20 Jan 2021 13:20:43

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:17:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:17:12
Data point term sent to Coder	System	20 Jan 2021 13:21:44
User entered 'zofran'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '4'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:42:52
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:43
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:38
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:07:24
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User entered empty.	System	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User entered empty.	System	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:07
User entered empty.	System	20 Jan 2021 13:21:18

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:26:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:26:04
Data point term sent to Coder	System	20 Jan 2021 13:22:45
User entered 'lovenox'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '30'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Q12H'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:43:30
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:56
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:51:49
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:07:32
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User entered empty.	System	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User entered empty.	System	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:40:56
User entered empty.	System	20 Jan 2021 13:21:59

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:58:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:58:04
Data point term sent to Coder	System	20 Jan 2021 13:28:50
User entered 'decadron'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:59:11
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 15:40:25
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:07:47
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '6'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '20 Dec 2020' reason for change: Data Entry Error	Marlee Smith (b) (4)	01 Apr 2021 15:40:19
User entered '20 Oct 2020'	Marlee Smith (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '26 Dec 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 15:40:19
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	20 Jan 2021 15:00:20
User entered '26 Oct 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 15:00:20
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	20 Jan 2021 13:28:03
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:43:39
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:52:50
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:52:39
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:07:54
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 15:00:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 15:00:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 15:00:20
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:28:03
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User entered '1'	System	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User entered '1'	System	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:01
User entered '804 (804)'	System	20 Jan 2021 13:28:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 06:13:52
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 Mar 2021 06:13:52
Data point term sent to Coder	System	09 Mar 2021 06:12:22
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:11:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:03:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:03:04
Data point term sent to Coder	System	20 Jan 2021 13:29:51
User entered 'remdesivir'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 14:09:25
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'This is per medical records ' (Site from DM).	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 15:25:34
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:08:56
User entered '75'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered 'twice daily (BID)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:42:31
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Error, updated.' (Site from DM).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:12:34
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:11:47
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:09:04
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered '20 Dec 2020'	Marlee Smith (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:10:40
User entered '24 Dec 2020'	Marlee Smith (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:40
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:43:48
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:53:05
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:53:00
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:09:12
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User entered '2'	System	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User entered '1'	System	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:08
User entered '804 (804)'	System	20 Jan 2021 13:28:52

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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) (b) (4)	09 Mar 2021 12:49:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 12:49:55
Data point term sent to Coder	System	09 Mar 2021 06:11:21
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:11:14
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) (b) (4)	20 Jan 2021 14:11:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:11:14
Data point term sent to Coder	System	20 Jan 2021 13:29:51
User entered 'Ceftriaxone'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 06:11:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 06:11:14
User entered '1' reason for change: Data Entry Error	Kayla Peay (b) (4)	09 Mar 2021 06:11:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	20 Jan 2021 13:29:28
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 06:11:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 06:11:14
User entered 'g (g)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:11:14
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:29:28
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 06:11:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 06:11:14
User entered 'other (OTHER)' reason for change:	Kayla Peay (b) (4)	09 Mar 2021 06:11:14
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:29:28
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Q24H' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:11:14
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 06:11:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 06:11:14
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:11:14
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:29:28
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '23 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:43:55
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:53:20
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:53:14
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:09:23
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User entered empty.	System	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User entered empty.	System	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:15
User entered empty.	System	20 Jan 2021 13:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:03:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:03:49
Data point term sent to Coder	System	09 Mar 2021 06:04:20
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:03:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:56:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:56:04
Data point term sent to Coder	System	20 Jan 2021 13:30:52
User entered 'azithromycin'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Viral Pneumonia' reason for change:	Kayla Peay (b) (4)	09 Mar 2021 06:03:58
Data Entry Error	(b) (4)	
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 07:43:03
Query 'Data is required. Please complete.' answered with 'Not provided in records. Unknown.' (Site from System).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:02:31
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:29:54
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 07:43:05
Query 'Data is required. Please complete.' answered with 'Not provided in records. Unknown. ' (Site from System).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:02:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:29:54
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 06:03:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 06:03:58
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:03:58
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:29:54
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 07:43:08
Query 'Data is required. Please complete.' answered with 'Unknown' (Site from System).	Kayla Peay (b) (4)	09 Mar 2021 06:03:05
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:29:54
User entered empty.	Marlee Smith (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	09 Mar 2021 06:05:54
User entered '16 Nov 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:05:54
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	20 Jan 2021 13:29:54
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 06:05:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 06:05:54
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:05:54
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:29:54
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	09 Mar 2021 06:07:11
User entered '21 Nov 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:07:11
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	09 Mar 2021 06:05:54
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:44:06
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:53:34
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:53:28
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:09:34
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User entered empty.	System	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User entered empty.	System	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:21
User entered empty.	System	20 Jan 2021 13:29:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User closed query 'Per MM, please provide the dose, units, frequency and route of medication ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:43:39
Query 'Per MM, please provide the dose, units, frequency and route of medication ' answered with 'Details were not in medical records' (Site from DM).	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 17:25:24
User opened query 'Per MM, please provide the dose, units, frequency and route of medication ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 20:29:25
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)	20 Jan 2021 13:58:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 13:58:03
Data point term sent to Coder	System	20 Jan 2021 13:30:52
User entered 'dexamethasone'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User entered 'COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 07:43:44
Query 'Data is required. Please complete.' answered with 'Unknown' (Site from System).	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 06:09:22
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:30:22
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 07:43:46
Query 'Data is required. Please complete.' answered with 'Unknown' (Site from System).	Kayla Peay (b) (4)	09 Mar 2021 06:09:29
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:30:22
User entered empty.	Marlee Smith (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 07:43:49
Query 'Data is required. Please complete.' answered with 'Unknown' (Site from System).	Kayla Peay (b) (4)	09 Mar 2021 06:09:36
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 13:30:22
User entered empty.	Marlee Smith (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 07:43:52
Query 'Data is required. Please complete.' answered with 'Unknown' (Site from System).	Kayla Peay (b) (4)	09 Mar 2021 06:09:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Jan 2021 13:30:22
	Marlee Smith (b) (4)	20 Jan 2021 13:30:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User entered '20 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User entered '29 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:09:57
User closed query 'er DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:44:21
Query 'er DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:53:49
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:53:43
User opened query 'er DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:10:18
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User entered empty.	System	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User entered empty.	System	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:29
User entered empty.	System	20 Jan 2021 13:30:22

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Apr 2021 13:45:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:45:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:10:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:04:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:04:04
Data point term sent to Coder	System	20 Jan 2021 13:31:52
User entered 'Sodium Chloride 0.9%'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User closed query 'Per DM CLR: Please review AE eCRF's AE #3 VIRAL PNEUMONIA DUE TO COVID 19 (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:47:01
Query 'Per DM CLR: Please review AE eCRF's AE #3 VIRAL PNEUMONIA DUE TO COVID 19 (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:54:07
User opened query 'Per DM CLR: Please review AE eCRF's AE #3 VIRAL PNEUMONIA DUE TO COVID 19 (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:10:39
User entered 'Pneumonia Due to COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered '250'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered 'mL (mL)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered 'IV'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered '19 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Mar 2021 15:54:41
User entered '24 Jan 2021' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:54:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Mar 2021 15:54:36
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	04 Mar 2021 15:54:36
User entered '24 2021' (non-conformant).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:54:36
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	20 Jan 2021 13:31:40
User entered '24 Jan 2021'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:10:01
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:44:48
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:54:26
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:54:18
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:10:46
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User entered empty.	System	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User entered empty.	System	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:53
User entered empty.	System	20 Jan 2021 13:31:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:01:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:01:05
Data point term sent to Coder	System	20 Jan 2021 13:32:53
User entered 'oxygen'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered 'No (N)'	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered 'pneumonia due to COVID 19'	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered '5'	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered 'Other (OTHER)'	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered 'liters'	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered empty.	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered empty.	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered '19 Dec 2020'	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered '0'	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User entered 'No (N)'	Marlee Smith (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Mar 2021 15:55:00
User entered '24 Jan 2021' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:55:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Mar 2021 15:54:51
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	04 Mar 2021 15:54:51
User entered '24 2021' (non-conformant).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:54:51
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	20 Jan 2021 13:32:36
User entered '24 Jan 2021'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:42:15
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:44:53
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:54:57
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 15:54:51
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:10:56
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User entered empty.	System	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User entered empty.	System	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:41:57
User entered empty.	System	20 Jan 2021 13:32:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
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) (b) (4)	09 Mar 2021 05:32:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 05:32:51
Data point term sent to Coder	System	09 Mar 2021 05:32:15
User entered 'Ceftriaxone'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Sepsis'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'l'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'g (g)'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'other (OTHER)'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Q24H'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Intravenous (INTRAVENOUS)'	Kayla Peay (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '16 Nov 2020'	Kayla Peay (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '27 Nov 2020'	Kayla Peay (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User entered empty.	System	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User entered empty.	System	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:09
User entered empty.	System	09 Mar 2021 05:31:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per Medical Records subject received zinc/vit C. Please add zinc to con-meds.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:15:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:15:39
Query 'Per Medical Records subject received zinc/vit C. Please add zinc to con-meds.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:47
User opened query 'Per Medical Records subject received zinc/vit C. Please add zinc to con-meds.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:17:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:12:05
Data point term sent to Coder	System	07 Apr 2021 15:41:02
User entered 'Vitamin C3'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered 'supplement'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered '1000'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered 'three times daily (TID)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered '17 Nov 2020'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:05
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User entered '3'	System	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User entered '1'	System	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:14
User entered '804 (804)'	System	07 Apr 2021 15:40:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:25:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:25:48
Data point term sent to Coder	System	07 Apr 2021 18:24:50
User entered 'Zinc'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'supplement'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '220'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '17 Nov 2020'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '0'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:19:47
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User entered '1'	System	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User entered '1'	System	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:18
User entered '804 (804)'	System	07 Apr 2021 18:24:08

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Query 'Per MM: Per protocol section 6.4.3 (immunoglobins and/or any blood products administered during the study period may determine the evaluability in the per-protocol analysis. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:40:47
User opened query 'Per MM: Per protocol section 6.4.3 (immunoglobins and/or any blood products administered during the study period may determine the evaluability in the per-protocol analysis. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 16:45:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:12:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: PLASMA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:12:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:12:55
Data point term sent to Coder	System	13 Apr 2021 12:56:32
User entered 'convalescent plasma'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered 'Hyponatremia'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered 'unk'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 14:06:47
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Marlee Smith (b) (4)	13 Apr 2021 12:56:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Apr 2021 12:56:03
User entered empty.	System	13 Apr 2021 12:56:03
	Marlee Smith (b) (4)	13 Apr 2021 12:56:03
	(b) (4)	

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered 'once (ONCE)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered empty.	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered '19 Nov 2020'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered '0'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered '19 Nov 2020'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:57
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User entered empty.	System	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User entered empty.	System	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:25
User entered empty.	System	13 Apr 2021 12:56:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:52:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:52:32
Data point term sent to Coder	System	20 Apr 2021 14:23:24
User entered 'Enoxaparin'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered 'Worsening COVID 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered '30'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered 'twice daily (BID)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered 'IV'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User entered '2'	System	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User entered '1'	System	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:34
User entered '804 (804)'	System	20 Apr 2021 14:22:54

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: ESCITALOPRAM [ESCITALOPRAM OXALATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:59:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:59:34
Data point term sent to Coder	System	20 Apr 2021 14:24:25
User entered 'Escitalopram oxalate'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered '10'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered '24 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:48
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User entered '1'	System	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User entered '1'	System	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:43:51
User entered '804 (804)'	System	20 Apr 2021 14:23:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:09:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:09:52
Data point term sent to Coder	System	20 Apr 2021 14:26:26
User entered 'Furosemide'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered '40'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered '22 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered '24 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User entered '1'	System	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User entered '1'	System	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:01
User entered '804 (804)'	System	20 Apr 2021 14:26:01

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:09:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:09:52
Data point term sent to Coder	System	20 Apr 2021 14:27:27
User entered 'Furosemide'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered '20'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered '26 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User entered '1'	System	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User entered '1'	System	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:09
User entered '804 (804)'	System	20 Apr 2021 14:27:03

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:11:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:11:45
Data point term sent to Coder	System	20 Apr 2021 14:28:48
User entered 'Guaifenesin ER'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered '1200'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered '24 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:31
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User entered '1'	System	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User entered '1'	System	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:26
User entered '804 (804)'	System	20 Apr 2021 14:27:46

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:12:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:12:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:11:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:11:45
Data point term sent to Coder	System	20 Apr 2021 14:28:54
User entered 'Guaifenesin ER'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered '600'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered '17 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered '24 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:29
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User entered '1'	System	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User entered '1'	System	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:29
User entered '804 (804)'	System	20 Apr 2021 14:28:36

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:02:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:02:43
Data point term sent to Coder	System	20 Apr 2021 14:29:55
User entered 'ipoamidol'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered '80'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered 'mL (mL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered 'once (ONCE)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered 'IV'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered '23 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered '23 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:27
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User entered empty.	System	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User entered empty.	System	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:44:39
User entered empty.	System	20 Apr 2021 14:29:28

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:28:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:28:41
Data point term sent to Coder	System	20 Apr 2021 14:30:56
User entered 'Potassium chloride sr'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '20'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mEq'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'every 2 hours'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '24 Nov 2020'	Marlee Smith (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '24 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User entered empty.	System	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User entered empty.	System	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:12
User entered empty.	System	20 Apr 2021 14:30:53

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:28:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:28:42
Data point term sent to Coder	System	20 Apr 2021 14:31:57
User entered 'potassium chloride sr tablet'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '40'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mEq'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'once (ONCE)'	Marlee Smith (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User entered empty.	System	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User entered empty.	System	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:47:53
User entered empty.	System	20 Apr 2021 14:31:47

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROTIGOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:12:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:12:39
Data point term sent to Coder	System	20 Apr 2021 14:33:01
User entered 'rotigotine'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '4'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Transdermal (TRANSDERMAL)'	Marlee Smith (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '17 Nov 2020'	Marlee Smith (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '26 Nov 2020'	Marlee Smith (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User entered '1'	System	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User entered '1'	System	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:04
User entered '804 (804)'	System	20 Apr 2021 14:32:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:31:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:31:27
Data point term sent to Coder	System	20 Apr 2021 14:34:02
User entered 'SALINE PERIPHERAL FLUSH'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '10'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mL (mL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'once (ONCE)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'IV'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '23 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '23 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User entered empty.	System	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User entered empty.	System	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:48:19
User entered empty.	System	20 Apr 2021 14:33:34

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:32:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:32:23
Data point term sent to Coder	System	20 Apr 2021 14:35:03
User entered 'sodium chloride flush'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '40'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mL (mL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'IV'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '27 Nov 2020'	Marlee Smith (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User entered empty.	System	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User entered empty.	System	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:24
User entered empty.	System	20 Apr 2021 14:34:26

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:05:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:05:40
Data point term sent to Coder	System	20 Apr 2021 14:36:04
User entered 'valsartan'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '320'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '17 Nov 2020'	Marlee Smith (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '27 Nov 2020'	Marlee Smith (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User entered '1'	System	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User entered '1'	System	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:50
User entered '804 (804)'	System	20 Apr 2021 14:35:04

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:01:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:01:32
Data point term sent to Coder	System	20 Apr 2021 14:36:04
User entered 'zinc sulfate'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '220'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '17 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '27 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User entered '1'	System	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User entered '1'	System	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:49:58
User entered '804 (804)'	System	20 Apr 2021 14:35:42

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 15:59:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 15:59:31
Data point term sent to Coder	System	20 Apr 2021 14:37:06
User entered 'zolpidem'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '5'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '17 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '23 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User entered '1'	System	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User entered '1'	System	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:18
User entered '804 (804)'	System	20 Apr 2021 14:36:24

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 15:56:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 15:56:28
Data point term sent to Coder	System	20 Apr 2021 14:48:15
User entered 'Albuterol'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '90'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'ug (ug)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Q6H'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '19 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '24 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User entered empty.	System	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User entered empty.	System	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:50:31
User entered empty.	System	20 Apr 2021 14:47:51

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:02:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:02:38
Data point term sent to Coder	System	20 Apr 2021 14:49:17
User entered 'ascorbic acid'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '1000'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '20 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '24 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User entered '1'	System	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User entered '1'	System	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:15
User entered '804 (804)'	System	20 Apr 2021 14:48:40

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
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: CHOLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 14:50:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 14:50:35
Data point term sent to Coder	System	20 Apr 2021 14:50:20
User entered 'cholecalciferol'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'worsening of covid 19'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '1000'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '20 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered '24 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:14:35
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User entered '1'	System	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User entered '1'	System	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:51:11
User entered '804 (804)'	System	20 Apr 2021 14:49:31

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:32:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:13:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:00:29
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	24 Sep 2020 21:02:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 13:18:12
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	06 Aug 2020 13:00:05

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:32:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered '16 Nov 2020'	Marlee Smith (b) (4)	20 Jan 2021 13:33:51
	(b) (4)	

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:32:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered 'ct of chest'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:33:51

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:33:51

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:32:46

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:33:51

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:32:46

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered '16 Nov 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:19

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:32:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered 'echocardiogram'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:19

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:19

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:32:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:19

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:32:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered '19 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:36

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:32:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered 'XR chest'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:36

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:36

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:32:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:36

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:32:46

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:45
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered '20 Dec 2020'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:57

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:32:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:45
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered 'convalescent plasma'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:57

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:45
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Per DM CLR: Please review if this Con Proc was done for AE#3 VIRAL PNEUMONIA DUE TO COVID 19. If so, ensure action taken reflects this procedure (ie, Other Action Taken=Concomitant Procedure). Else, there is no AE condition that matches this procedure. Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 09:50:11
Query 'Per DM CLR: Please review if this Con Proc was done for AE#3 VIRAL PNEUMONIA DUE TO COVID 19. If so, ensure action taken reflects this procedure (ie, Other Action Taken=Concomitant Procedure). Else, there is no AE condition that matches this procedure. Review and update necessary ecrfs as appropriate. ' answered with 'This is correct. The AE condition is COVID positive. ' (Site from DM).	Sara Poff (b) (4) (b) (4)	03 Mar 2021 01:14:07
User opened query 'Per DM CLR: Please review if this Con Proc was done for AE#3 VIRAL PNEUMONIA DUE TO COVID 19. If so, ensure action taken reflects this procedure (ie, Other Action Taken=Concomitant Procedure). Else, there is no AE condition that matches this procedure. Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:14:25
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:57

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:32:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:45
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:06:50
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Jan 2021 13:34:57

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:32:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:15:39
User entered '19 Nov 2020'	Kayla Peay (b) (4)	09 Mar 2021 05:01:58

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:32:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
User closed query 'Please indicate what con-med has been added for hyperglycemia correction, as it does not appear to be listed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:33:35
Query 'Please indicate what con-med has been added for hyperglycemia correction, as it does not appear to be listed.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	13 Apr 2021 12:54:18
User opened query 'Please indicate what con-med has been added for hyperglycemia correction, as it does not appear to be listed.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:39:21
User closed query 'Should a corresponding concomitant medication be listed in con-meds for this procedure on 19Nov20?' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:39:21
Query 'Should a corresponding concomitant medication be listed in con-meds for this procedure on 19Nov20?' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	12 Apr 2021 17:22:58
User opened query 'Should a corresponding concomitant medication be listed in con-meds for this procedure on 19Nov20?' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:17:33
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:15:39
User entered 'Hyperglycemia Correction'	Kayla Peay (b) (4) (b) (4)	09 Mar 2021 05:01:58

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:32:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:15:39
User entered 'Adverse Event (AE)'	Kayla Peay (b) (4)	09 Mar 2021 05:01:58

US3722066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:32:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:15:39
User entered empty.	Kayla Peay (b) (4)	09 Mar 2021 05:01:58

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
User entered '18/Nov/2020 18:09'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
User entered '20/Nov/2020 16:05'	System	20 Nov 2020 16:06:01

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 19:07:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 16:06:01

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Death

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered '25/Nov/2020 19:07'	System	25 Nov 2020 19:07:34

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:32:07
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 19:07:34

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered '14/Dec/2020 15:36'	System	14 Dec 2020 21:36:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:32:07
User entered 'I'	(b) (4), (b) (6)	14 Dec 2020 21:36:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered '16/Feb/2021 13:32'	System	16 Feb 2021 18:32:21

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 22:09:28
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 18:32:21

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered '04/Mar/2021 22:09'	System	04 Mar 2021 22:09:43

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:18
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 22:09:43

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered '09/Mar/2021 13:37'	System	09 Mar 2021 18:37:17

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:18
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 18:37:17

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered '10/Mar/2021 10:20'	System	10 Mar 2021 15:20:37

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 21:52:15
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 15:20:37

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered '11/Mar/2021 16:52'	System	11 Mar 2021 21:52:36

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 15:01:10
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 21:52:36

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered '15/Mar/2021 11:01'	System	15 Mar 2021 15:01:31

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 15:11:28
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 15:01:31

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered '07/Apr/2021 10:11'	System	07 Apr 2021 15:11:47

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:46:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:14
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 15:11:47

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:18:05
User entered '08/Apr/2021 09:46'	System	08 Apr 2021 13:46:17

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:34:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:18:05
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 13:46:17

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:05
User entered '13/Apr/2021 14:34'	System	13 Apr 2021 18:34:28

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:15:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:11:05
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 18:34:28

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (14)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:15:16
User entered '16/Apr/2021 09:15'	System	16 Apr 2021 14:15:38

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (14)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:15:16
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 15:17:41
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 14:15:38

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'USA-US083-2020-MRNA-1273-P301000007'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'Yes (Y)'	System	19 Nov 2020 13:37:55
Un-reviewed for Safety.	System	19 Nov 2020 13:33:43
User entered 'No (N)'	System	19 Nov 2020 13:33:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Yes (Y)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'No (N)'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Luis'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'De La Cruz'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '2 Roper Corners Cir'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'Greenville'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered 'SC'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:09:35
User entered '29615'	System	18 Nov 2020 18:08:44

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:18:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:05:46
User entered 'US'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '15'	System	22 Apr 2021 15:17:59
User entered '14'	System	16 Apr 2021 14:15:38
User entered '13'	System	13 Apr 2021 18:34:28
User entered '12'	System	08 Apr 2021 13:46:17
User entered '11'	System	07 Apr 2021 15:11:47
User entered '10'	System	15 Mar 2021 15:01:31
User entered '9'	System	11 Mar 2021 21:52:36
User entered '8'	System	10 Mar 2021 15:20:37
User entered '7'	System	09 Mar 2021 18:37:17
User entered '6'	System	04 Mar 2021 22:09:43
User entered '5'	System	16 Feb 2021 18:32:21
User entered '4'	System	14 Dec 2020 21:36:42
User entered '3'	System	25 Nov 2020 19:07:34
User entered '2'	System	20 Nov 2020 16:06:01
User entered '1'	System	18 Nov 2020 18:09:42

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (15)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:15:16
User entered '22/Apr/2021 11:17'	System	22 Apr 2021 15:17:59

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000007

Form: Safety Report Form (15)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:15:16
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 15:17:59

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'USA-US083-2020-MRNA-1273-P301000012'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:44:47
DataPoint Un-verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:39
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Luis'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'De La Cruz'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '2 Roper Corners Cir'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Greenville'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'SC'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '29615'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 14:14:50
User entered 'US'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Mar 2021 22:10:07
User entered '3'	System	16 Feb 2021 18:39:09
User entered '2'	System	21 Jan 2021 14:15:02
User entered '1'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'USA-US083-2020-MRNA-1273-P301000012'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:44:47
DataPoint Un-verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:39
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Luis'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'De La Cruz'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '2 Roper Corners Cir'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Greenville'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'SC'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '29615'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 14:14:50
User entered 'US'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Mar 2021 22:10:07
User entered '3'	System	16 Feb 2021 18:39:09
User entered '2'	System	21 Jan 2021 14:15:02
User entered '1'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
User entered '28/Dec/2020 15:06'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 14:14:50
User entered 'I'	(b) (4), (b) (6)	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'USA-US083-2020-MRNA-1273-P301000012'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:44:47
DataPoint Un-verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:39
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Luis'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'De La Cruz'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '2 Roper Corners Cir'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Greenville'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'SC'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '29615'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 14:14:50
User entered 'US'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Mar 2021 22:10:07
User entered '3'	System	16 Feb 2021 18:39:09
User entered '2'	System	21 Jan 2021 14:15:02
User entered '1'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
User entered '21/Jan/2021 14:14'	System	21 Jan 2021 14:15:02

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:38:56
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:26
User entered 'I'	(b) (4), (b) (6)	21 Jan 2021 14:15:02

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'USA-US083-2020-MRNA-1273-P301000012'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:44:47
DataPoint Un-verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:39
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Luis'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'De La Cruz'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '2 Roper Corners Cir'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Greenville'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'SC'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '29615'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 14:14:50
User entered 'US'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Mar 2021 22:10:07
User entered '3'	System	16 Feb 2021 18:39:09
User entered '2'	System	21 Jan 2021 14:15:02
User entered '1'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:44:28
User entered '16/Feb/2021 13:39'	System	16 Feb 2021 18:39:09

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:44:28
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 22:09:53
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 18:39:09

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'USA-US083-2020-MRNA-1273-P301000012'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:44:47
DataPoint Un-verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:39
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Yes (Y)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'No (N)'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Luis'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'De La Cruz'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '2 Roper Corners Cir'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'Greenville'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered 'SC'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:06:05
User entered '29615'	System	28 Dec 2020 15:01:46

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:21:26
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 14:14:50
User entered 'US'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	04 Mar 2021 22:10:07
User entered '3'	System	16 Feb 2021 18:39:09
User entered '2'	System	21 Jan 2021 14:15:02
User entered '1'	System	28 Dec 2020 15:06:30

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:32:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:44:24
User entered '04/Mar/2021 22:10'	System	04 Mar 2021 22:10:07

US3722066

Folder: SAE USA-US083-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:32:46

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:44:24
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 22:10:07